CONTAMINATED FOOD: PRIVATE SECTOR ACCOUNTABILITY

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

FEBRUARY 26, 2008

Serial No. 110–92

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SUBMITTED MATERIAL

CONTAMINATED FOOD: PRIVATE SECTOR ACCOUNTABILITY

TUESDAY, FEBRUARY 26, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2322 of the Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Members present: Representatives Stupak, DeGette, Doyle, Schakowsky, Inslee, Dingell (ex officio), Shimkus, Walden, Murphy, Burgess, Blackburn and Barton (ex officio).

Staff present: Scott Scholegel, David Nelson, Kevin Barstow, Richard Wilfong, John Sopko, Kyle Chapman, Alan Slobodin, Krista Carpenter, Whitney Drew.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr.STUPAK. This meeting will come to order.

Today we have a hearing entitled "Contaminated Food: Private Sector Accountability." Each member will be recognized for a five minute opening statement. I will begin.

Today we hold the fifth subcommittee hearing on the safety of our Nation's food supply. Although it was purely coincidental that this hearing was set before the largest beef recall in American history. It is not a coincidence that recalls of this magnitude are escalating. Since starting our investigations Americans have witnessed one food safety disaster after another. In the last 18 months alone we have seen in August and September of 2006, E. coli in bagged spinach sickened 204 people and killed three. In September of 2006 salmonella found in tomatoes sickened 183 people. In December 2006 lettuce contaminated with E. coli at Taco Bell and Taco John restaurants sickened 152 people. In February 2007 Peter Pan peanut butter contaminated with salmonella sickened 425 people. In February and March 2007, 100 brands of tainted pet food were recalled after sickening and killing thousands of pets. In June 2007 Veggie Booties snacks contaminated with salmonella caused 65 illnesses. In July 2007, 90 canned food products with botulism contamination were recalled after sickening eight people. In August 2007, almost a year and a half after the last spinach E. coli outbreak, another nationwide recall of fresh spinach occurred following discovery of salmonella in test batches. In October of 2007 frozen pot pies carrying salmonella were recalled after illnesses

were reported in 31 states. In September of 2007 nearly 22 million pounds of beef were recalled after E. coli contamination was found. And finally, just over a week ago, nearly 144 million pounds of beef were recalled by Westland/Hallmark Meat Packing Company after being determined to be unfit for human consumption. Our food safety system is broken. So called voluntary compliance, relying on the food industry to place safety before profits, does not appear to be working. The budgets and regulatory policies of this Administration have crippled both the Food and Drug Administration and the Food Safety and Inspection Service of the United States Department of Agriculture. In fact, some 76 million Americans, almost one out of every four Americans, are affected each year by illnesses from contaminated food. Since sickness from contaminated food is largely preventable this committee has actively pushed the public and private sectors to focus on preventing this epidemic.

What have we learned so far? We found a fragmented food safety program suffering from willfully inadequate resources, inconsistent oversights, and ineffective coordination. In December the FDA's own science board report noted that FDA's Food Safety Program has put American lives at risk, and the FDA "does not have the capacity to ensure the safety of food for our Nation." We have also learned that the problems are not just limited to the FDA. The once vaulted USDA seal of wholesomeness can no longer be relied upon to protect consumers. USDA, despite having about four times the food safety budget of FDA and a network of inspectors in many, if not all meat processing facilities, is also failing to protect Americans. Last week's extraordinary recall of over 143 million pounds of beef by Westland/Hallmark Meat Packing Company follows more than 20 other beef recalls in the preceding 20 months. Nearly two meat recalls per month. My colleagues and I are fully aware that the product recalls by the USDA does not indicate success, rather each recall means that the system has failed. Recalls tell us that contaminated beef made it into the marketplace, restaurants, schools and our kitchen tables. Last fall our hearing drew attention to 22 million pounds of beef that was recalled that was packaged in carbon monoxide, deceiving consumers into thinking the meat was fresh, wholesome and free of contaminants. I am troubled to tell my colleagues that despite our investigation, and despite one major retailer's request to label their meat as having been packed with carbon monoxide, the USDA is still refusing to allow retailers to label their meat as such.

Today's hearing focuses on the role of private industry and protecting our Nation's food supply. Responsibility for supplying safe and wholesome foods does not rest solely with the government. It is always the food processor that has the first opportunity to ensure the safety of their product and prevent these tragic food illnesses. We intend to ask food processors what they have learned from the food recalls, illnesses and deaths of last year, what they are doing to protect the American consumer and ensure their food is safe. Some of the food processors whose products were recalled last year will testify today. Eating vegetables, such as spinach, was once every parent's refrain. But as we learned last year, eating vegetables and spinach nearly led to the serious injury and death of defenseless children. Unfortunately, the problems associated

with Salinas Valley, known as America's salad bowl, continue to plague us. Is America any safer today? Hopefully the CEO of Dole, the Nation's largest distributor of E. coli spinach that sickened and killed people last year, will tell us what he is doing to stop these problems. ConAgra, a firm that blamed the problems relating to Peter Pan peanut butter on a leaky roof in testimony before us last April, is also back to explain why the same strain of salmonella got in their peanut butter jars six months after the leak was fixed. ConAgra still has to explain to the American people how salmonella infected its Banquet brand turkey pot pies. We also need to understand from ConAgra and their supplier Butterball how fully cooked turkey could sicken people who ate their pot pies. We also planned to have asked Steve Mendell, the CEO of Hallmark and Westland Company, to explain how he could produce and ship over 143 million pounds of raw and frozen beef products that the USDA determined was unfit for human consumption. Hallmark/Westland's February 17 recall is the largest meat recall in the Nation's history. Fifty-five million pounds of this meat was shipped to feed children in federally sponsored school lunch programs. How could children and seniors be fed beef from cattle that could not legally be slaughtered. USDA inspectors were at the plant. Where were they? Why didn't Federal inspectors catch the illegal slaughter of downer cows before millions of children were put at risk of mad cow disease and other health problems from eating meat from cows that were too sick to even stand up?

We will also hear from the CEO of Bumblebee and New Era about the deadly botulism bacteria that were found in their food. We need to know how botulism, a very deadly but rarely found bacteria, survived the sterilization process required for low acid canned foods in the Bumblebee plant in Georgia and the New Era facility in Michigan. I believe this is the first time in over 30 years that botulism has been discovered in our food. If we can no longer trust our food companies to provide us with food that is supposed to be pasteurized, then America's food safety has sunk to a new low. How many other foods that are supposed to be sterilized before they are being sent to the grocery stores, but are not being pasteurized before being sold to American consumers.

Today we will also have more testimony of banned antibiotics found in imported seafood that the FDA is unable to keep off our tables.

We will also have with us today a witness from a private laboratory that tests imported food for safety. We expect to learn how easily companies can manipulate the current inspection system to allow contaminated imported food into our supply. Fifteen years ago America's trust in the food supply was shattered when four children died and more than 700 people became sick after eating Jack-In-The-Box hamburgers. USDA responded to this tragedy in 1995 with creation of an industry-supported Hazard Analysis Critical Control Point, or HACCP. The HACCP system was promoted as a science-based strategy for protecting public health. Although the scientific principals of HACCP remain sound, many experts contend that it actually decreased Federal oversight, because of industry's self reliance on self inspection under HACCP.

Today our food safety system is broken. The overarching question for the corporate CEOs testifying today is simply how do we fix our critical food safety net? Chairman Dingell, myself, and a number of our colleagues are determined to restore confidence in our food safety system. We need your support. I hope today is a start to correct the problems that created the litany of recalls and illnesses of food recalls last year. Members of this committee look forward to working with you in this effort.

My opening statement is complete. Next we turn to Mr. Shimkus, from Illinois, for his opening statement, please, sir.

[The prepared statement of Hon. Bart Stupak follows:]

STATEMENT OF THE HONORABLE BART STUPAK SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS "CONTAMINATED FOOD: PRIVATE SECTOR ACCOUNTABILITY."

FEBRUARY 26, 2008

Today we hold the fifth Subcommittee hearing on the safety of our Nation's food supply. Although it was purely coincidental that this hearing was set before the largest beef recall in American history, it is not a coincidence that recalls of this magnitude are escalating.

Since starting our investigation, Americans have witnessed one food safety disaster after another. In the last 18 months:

- In August and September 2006, *E. coli* in bagged spinach sickened 204 people and killed three.
- In September 2006, *Salmonella* found in tomatoes sickened 183 people.
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- In October 2007, frozen pot pies carrying *Salmonella* were recalled after illnesses were reported in 31 States.
- In September 2007, nearly 22 million pounds of beef were recalled after *E. coli* contamination was found.

- Finally, just over a week ago, nearly 144 million pounds of beef were recalled by Westland/Hallmark Meat Packing Company after being determined to be unfit for human consumption.

Our food safety system is broken. So-called voluntary compliance—relying on the food industry to place safety before profits—does not appear to be working. The budgets and regulatory policies of this Administration have crippled both the Food and Drug Administration (FDA) and, the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). In fact, some 76 million Americans – 1 out of every 4 - are affected each year by illness from contaminated food.

Since sickness from contaminated food is largely preventable, this Committee has actively pushed the public and private sectors to focus on preventing this epidemic. What have we learned so far? We have found a fragmented food safety system suffering from woefully inadequate resources, inconsistent oversight, and ineffective coordination. In December the FDA's own Science Board report noted that FDA's food safety program has put American lives at risk and the FDA "does not have the capacity to ensure the safety of food for the nation."

We have also learned that the problem is not limited to just the FDA. The once vaunted USDA seal of wholesomeness can no longer be relied upon to protect consumers. USDA, despite having about four times the food safety budget of FDA and a network of inspectors in many, if not all, meat processing facilities, is also failing to protect Americans. Last week's extraordinary recall of over 143 million pounds of beef by Westland/Hallmark Meat Packing Company follows more than 20 other beef recalls in the preceding 12 months – nearly 2 meat recalls per month.

My colleagues and I are fully aware that product recalls by the USDA do not indicate success; rather each recall means that the system has failed. Recalls tell us that contaminated beef made it into the marketplace, restaurants, schools and our kitchen tables.

Last fall's hearing drew attention to a 22 million pound recall that included beef packed in carbon monoxide deceiving consumers into thinking that the meat was fresh, wholesome, and free of contaminants. I am troubled to tell my colleagues that despite our investigation and despite one major retailer's request to label their meat as having been packed with carbon monoxide, the USDA is still refusing to allow retailers to label their meat as such.

Today's hearing focuses on the role of private industry in protecting our Nation's food supply. Responsibility for supplying safe and wholesome foods does not rest solely with the Government. It is always the food processor that has the first opportunity to ensure the safety of their product and prevent these tragic food illnesses. We intend to ask food processors what they have learned from food recalls, illnesses, and deaths of last year and what they are doing today to protect the American consumer and ensure their food is safe?.

Some of the food processors whose food products were recalled last year, will testify today. Eating vegetables such as spinach was once every parent's refrain. But as we learned last year, eating vegetables and spinach nearly led to the serious injury and death of a defenseless children. Unfortunately, the problems associated with the Salinas Valley, known as America's salad bowl, continue to plague us. Is America any safer today? Hopefully, the CEO of Dole, the largest distributor of the *E. coli* spinach that sickened and killed people last year, will tell us what he is doing to stop these problems.

ConAgra, a firm that blamed the problems relating to its Peter Pan peanut butter on a leaky roof in testimony before us last April, is also back to explain why the same strain of *Salmonella* got into their peanut butter jars six months after the leak was fixed. ConAgra still has to explain to the American people how *Salmonella* infected its Banquet brand turkey pot pies. We also need to understand from ConAgra and their supplier, Butterball, how fully cooked turkey could sicken people who ate their pot pies.

We also planned to ask Steve Mendell, the CEO of Hallmark/Westland Co., to explain how he could produce and ship over 143 million pounds of raw and frozen beef products that the USDA determined was "unfit for human consumption." Hallmark/Westland's February 17th recall is the largest meat recall in the history of the United States. Fifty-five million pounds of this meat was shipped to feed children in federally sponsored school lunch programs. How could children and seniors be fed beef from cattle that could not be legally slaughtered? USDA inspectors were in the plant. Where were they? Why didn't federal inspectors catch the illegal slaughter of downer cows before millions of children were put at risk of Mad Cow Disease and other health problems from eating meat from cows that were too sick to even stand up.

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Fifteen years ago, America's trust in its food supply was shattered when four children died and more than 700 people became sick after eating Jack-in-the-Box hamburgers. USDA responded to this tragedy in 1995 with creation of industry-supported Hazard Analysis Critical Control Point or HACCP system. HACCP was promoted as a science-based strategy for protecting public health. Although the scientific principles of HACCP remain sound, many experts contend that it actually has decreased Federal oversight because of industry reliance on self-inspection under HACCP.

Today our food safety system is broken. The overarching question for the corporate CEOs testifying today is simply how do we fix our critical food safety net? Chairman Dingell, myself, and a number of our colleagues are determined to restore confidence in our food safety system. We need your support. I hope today is a start to correct the problems that created the litany of recalls and illnesses of food recalls last year. Members of this committee look forward to working with you in this effort.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr.SHIMKUS. Thank you, Mr. Chairman. As you stated today this hearing is fifth in a series of food safety hearings conducted over the past year. And the hearing brings together a number of recent food safety cases representing four or five distinct issues. Import surveillance, adherence to good manufacturing practices, the role of Federal guidance and mandates and enforcement of and company adherence to existing rules and regulations. As the hearing title suggests the essential theme today is private sector accountability. Our job today is to shine the light on these cases before us to identify whether there were any deficiencies in private sector actions, and to determine what changes, if any, by the regulators or the regulated could have prevented the outbreaks from occurring. We will be hearing some alarming stories about food safety practices. We should keep some perspective on this. According to the Centers for Disease Control and Prevention there are approximately 76 million food borne illnesses a year, which result in an estimated 5,000 deaths and 325,000 hospitalizations. These numbers indicate that food safety regulation standards and guidelines should be reviewed and updated frequently and enforced to ensure that all Americans are eating wholesome and safe food. While any death or hospitalization is one too many, it is not so clear whether we are experiencing a significant across the board spike in food borne illness outbreaks compared with a decade ago. Date of last April from CDC surveillance showed that illnesses from consuming raw seafood, mostly oysters, have spiked well above the late 1990s. But the relatively low rate of salmonella and viral E. coli outbreaks, although rising in recent years, were still below the 1996 to 1998 baseline. We should nevertheless be constantly vigilant for ways to improve our food safety regulatory system. The goal is to reduce the risks of food borne illnesses while maintaining the wonderful variety, abundance, and value of our Nation's food supply.

Imports are our special regulatory challenge. But technology advances are providing tools that can help address the risks domestically. Due to advances in information technology such as pulsenet and foodnet the CDC and the State Health Departments now have access to and can input surveillance data into national databases that monitor and track food borne illnesses. These technologies instituted in the late 1990's serve as powerful investigative tools to help uncover the source of food borne illnesses and outbreaks in our country. Prior to these systems tracking food borne illnesses and tracing the illnesses back to the root sources was more cumbersome and incomplete. Now that we are doing a better job of tracking food borne illnesses we should work to make sure this information is put to maximum use to improve safety systems.

This hearing focuses mainly on several companies that have produced food products that have been contaminated by harmful pathogens including E. coli, salmonella and botulism. These contaminants can lead to human illnesses, especially in those who are immune, such as children and the elderly. Our witnesses today are divided into two panels, but are here for one reason. We all want to discern what both the public and private sector can do to reduce the risks of food borne illnesses. I understand that the American

public wants someone to be held accountable, corporate or otherwise. However, before we can determine what should be done, we need to answer some fundamental questions. What is the source of contamination in each one of these cases? Can it ever be identified? Can we identify deficiencies in the company practices that would have prevented or would prevent this harm in the future? Would increased federal regulations address these deficiencies, or it is merely a matter of closely adhering to existing rules and practices? Are some of the cases representative of bad actors that violated existing regulations and need penalties enforces against them? I have a hunch, Mr. Chairman, that we will find today a range of answers depending upon the case before us. For that reason I think one of difficult, but useful goals of this morning is to sort out clearly for the Director the separate lessons we can draw from each of these cases.

I look forward to the witnesses this morning, and the variety of perspectives and expertise. This promises to be an informative hearing. I yield back.

[The prepared statement of Hon. John Shimkus follows:]

STATEMENT OF HON. JOHN SHIMKUS

Thank you Mr. Chairman. As you stated, today's hearing is the fifth in a series of food safety hearings conducted over the past year. And the hearing brings together a number of recent food safety cases, representing four or five distinct issues: import surveillance, adherence to good manufacturing practices, the role of federal guidance and mandates, and enforcement of—and company adherence to—existing rules and regulations.

As the hearing title suggests a central theme today is private sector accountability. Our job is to shine a light on these cases before us to identify whether there were any deficiencies in private sector actions and to determine what changes, if any, by the regulators or the regulated could have prevented the outbreaks from occurring.

We will be hearing some alarming stories today about food safety practices. We should keep some perspective on this. According to the Centers for Disease Control and Prevention (CDC) there are approximately 76 million food-borne illnesses a year, which result in an estimated 5,000 deaths and 325,000 hospitalizations. These numbers indicate that food safety regulations, standards, and guidelines should be reviewed and updated frequently and enforced to ensure that all Americans are eating wholesome and safe food.

While any death or hospitalization is one too many, it is not so clear whether we are experiencing a significant across-the-board spike in food-borne illness outbreaks compared with a decade ago. Data last April from CDC surveillance showed that illnesses from consuming raw seafood (mostly oysters) have spiked well above the late 1990s, but that the relative rate of salmonella and virulent E. coli outbreaks—although rising in recent years—were still below the 1996–1998 baseline.

We should nevertheless be constantly vigilant for ways to improve our food-safety regulatory system. The goal is to reduce the risk of food borne illness, while maintaining the wonderful variety, abundance, and value of our nation's food supply.

Imports are a special regulatory challenge, but technology advances are providing tools that can help address the risks domestically. Due to advances in information technologies, including PulseNet and FoodNet, the CDC and the state health departments now have access to and can input surveillance data into national databases that monitor and track food borne illnesses. These technologies, instituted in the late 1990s, serve as powerful investigative tools to help uncover the sources of food borne illness outbreaks in our country.

Prior to these systems, tracking food borne illnesses and tracing the illnesses back to root sources was more cumbersome and incomplete. Now that we are doing a better job of tracking food borne illnesses, we should work to make sure this information is put to maximum use to improve safety systems.

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I have a hunch, Mr. Chairman, that we will find today a range of answers, depending on the case before us. For that reason, I think one of the difficult but useful goals for us this morning is to sort out clearly for the record the separate lessons we can draw from each of these cases.

I look forward to the witnesses this morning, and their variety of perspectives and expertise. This promises to be an informative hearing.

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Mr.STUPAK. Thank you, Mr. Shimkus.

Mr. Dingell, for an opening statement, please.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr.DINGELL. Good morning to the Chairman. Thank you for holding this hearing.

I commend you for the vigor of your oversight of food and drug and other important matters of concern to this Committee. Oversight of food safety is one of the most important undertakings of this Committee, and it appears that this is a subject that needs the most vigorous attention of the Committee.

Today we are going to hear from leading companies in the food processing industry about what does or does not work in safeguarding our food supply. Unfortunately we are forced to return to issues and to hear from witnesses from our prior hearing of last April. At that time ConAgra testified regarding the discovery of salmonella in their Peter Pan peanut butter. What we did not know then, due to FDA obfuscation and delay, was that this problem was more serious than we had been told. After the hearing we learned that many more jars containing the deadly bacteria had been found, and that some had been processed fully six months after ConAgra claimed that the problem had been fixed. Since last April's hearings we have learned of another problem with ConAgra. Apparently their Banquet brand of pot pies have made hundreds of Americans sick. While the source of this contamination is still in doubt, ConAgra blames Butterball, who claims that the turkeys for the pies was the source of the problem. Butterball disagrees and claims that their turkey is fully cooked before it is shipped. Ironically, the FDA has no opinion on the matter. Today we hope that these companies can clarify this issue and assure the consumer that their products are safe. We also hope that we will hear something from the FDA, which will enable us to have some confidence that they know what they are doing.

Last April we also heard testimony about contaminated lettuce and spinach. We were assured then that the problem was under control due to the issuance of new voluntary compliance standards. Since then, however, we have had two more recalls of leafy greens. We will hear from Dole Foods as well as from Mr. Brackett of the Grocery Manufacturers Association who recently retired as the head of food safety at FDA, and helped develop these voluntary standards. Suffice to say that we have questions about some of these proposals. And we also want to hear how voluntary standards can be made to work to protect the consumers. Apparently there is some evidence to the contrary here before us this morning.

We also will hear from two firms where botulism has been found in their low acid canned foods. This is very unusual. It is the first time in more than 30 years that such products have been infected with botulism in this country. One of these plants even had a USDA inspector on the premises for full-time. We also wanted to hear from the head of the California Meat Packing Company who recently recalled 143 million pounds of beef, including 55 million pounds destined for our school children. It appears that the head of this company has refused our offer to testify voluntarily. We will now have to consider whether we need to compel his appearance to probe how on-site USDA inspectors could have missed these safety problems and the inhumane treatment of animals who were slaughtered there.

Finally, Mr. Chairman, I would like to address the broader issue of industry responsibility. Under this Administration we have experimented with voluntary health and safety regulations to protect our food. Yet it appears that our food supply becomes more dangerous all the time both from imported products and from domestically produced products, sometimes contaminated by unwise imports from China and other places. It is clear that our regulatory system is broken. It is plain that Food and Drug does not have the personnel. It does not have the money. It does not have the resources to carry out its important responsibilities. It is also appearing to me that they do not have the leadership that is necessary to do the things that are required for the protection of the American consumer.

I am going to urge industry to provide serious recommendations today, and more importantly, to strongly support legislation that will ensure food safety. The time has passed for halfway measures or asking regulators to do more with less. I began listening to the rather plaintive remarks of the head of Food and Drug when Mr. Young was the head of that agency. And he used to call me up and tell me, Dingell, we are going to do a good job. We have a new system, which will make it possible for us to do the job better with less money. It turned out it was hooey, and he is no longer with the agency. This is a situation, then, which is serious. The health of the American people is at stake. I urge our witnesses and others in the industry to join with us in changing the current system. I can assure you that this will not be the last time that you will be before us testifying about another recall and another failure in protecting our Nation's food supply. I look forward to an explanation of what you have done, why this has happened and what you are

going to do to assure us that this will not occur again. Thank you, Mr. Chairman.

[The prepared statement of Hon. John Dingell follows:]

STATEMENT OF HON. JOHN D. DINGELL

Mr. Chairman, thank you for holding this hearing. Oversight of food safety is one of the most important undertakings of this Committee.

Today we will hear from leading companies in the food processing industry about what does or does not work in safeguarding our food supply. Unfortunately, we are forced to return to issues and hear from witnesses from our prior hearing last April.

At that time, ConAgra testified regarding the discovery of Salmonella in their Peter Pan peanut butter. What we did not know then, due to FDA obfuscation and delay, was that this problem was more serious than what we had been told. After the hearing, we learned that many more jars contained the deadly bacteria and some had been processed fully 6 months after ConAgra claimed they had fixed the problem.

Since last April's hearing, we have learned of another problem with ConAgra. Apparently, their Banquet brand pot pies have made hundreds of Americans sick, while the source of the contamination is still in doubt. ConAgra blames Butterball, which supplies the turkey for the pies. Butterball disagrees and claims their turkey is fully cooked before shipped. Ironically, the FDA has no opinion on the matter. Today, we hope those companies can clarify this issue and assure the consumer that their products are safe.

Last April, we also heard testimony about contaminated lettuce and spinach. We were assured then that the problem was under control due to the issuance of new voluntary compliance standards. Since then, however, we have had two more recalls of leafy greens.

We will hear from Dole Foods as well as from Mr. Brackett of the Grocery Manufacturers Association who recently retired as head of food safety at FDA and helped develop those voluntary standards. Suffice it to say, we have some questions about those proposals.

We also will hear from two firms where botulism has been found in their low acid canned foods. This is very unusual. It is the first time in more than 30 years that such products have been infected with botulism in this country. One of those plants even had a USDA inspector on premises full time.

We also wanted to hear from the head of the California meat packing company who recently recalled 143 million pounds of beef, including 55 million pounds destined for our school children. It appears he has refused our offer to testify voluntarily. We now will have to consider whether we need to compel his appearance to probe how on-site USDA inspectors could have missed these safety problems and the inhumane treatment of the animals that were slaughtered there.

Finally, Mr. Chairman, I would also like to address the broader issue of industry responsibility. Under this Administration, we have experimented with voluntary health and safety regulations to protect our food. Yet, our food supply becomes more dangerous all the time.

It is clear our regulatory system is broken. I urge industry to provide serious recommendations and, more importantly, strongly support legislation that will ensure food safety. The time has passed for half measures or asking regulators to do more with less. Our health is at stake. If you don't join us in changing the current system, I can assure you that this will not be the last time you join us in testifying about another recall and another failure in protecting our Nation's food supply.

Mr.STUPAK. Thank you, Mr. Dingell.

Mr. Barton, for an opening statement, please.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr.BARTON. Thank you, Mr. Chairman, for holding this hearing on the contaminated food and private sector accountability.

I want to say at the outset, and while there are partisan differences in the Congress on various issues, on this issue, the issue of food safety for the American people, there is no daylight between

Mr. Stupak, Mr. Dingell, Mr. Shimkus, myself and the Republicans and Democrats on this oversight, subcommittee and the full Committee.

If you go back not too many years ago most families, mine included, grew most of what they consumed. My grandparents and great-grandparents both grew up and lived on farms in central Texas. They grew their own—they raised their own cattle, chickens, pigs. Both of my great-grandmothers and grandmothers had huge truck gardens. I can remember in the early 50s if I wanted, when it was in season, if I wanted green beans or corn I went out and picked them and brought them in. And my grandmother shucked the corn and boiled it and split the green beans and we had—that is what we had. I doubt they are many families in America today that do that. We depend on a vast network of producers and distributors and processors so that when, like my 2½-year-old several days ago wanted a banana, I did not go out in the backyard since banana trees would not grow in Texas anyway. I went to the grocery store and bought some bananas. I think I paid 20 cents a pound for them or something.

It is absolutely imperative that the food safety, the food products on the shelves of our grocery stores, is beyond question. Now, I don't believe anybody in this room would say that you do not support that. Yet, when we look at the record, it is stunning how much impaired food is reaching our shelves and the dinner tables of American families. If statistics are to be believed in the last year 5,000 Americans died because they consumed contaminated food products. Most of those products were beef or seafood. A large number of the products apparently were imported from overseas, and a fair amount of that from the—from China.

I am working on a bipartisan basis to introduce legislation in the very near future that would give the Food and Drug Administration the authority to have jurisdiction outside the United States when necessary to protect our food supply and do food inspections. We have got a letter of support from the Administration. The Clinton Administration supported this type of legislation. There have been some court decisions that said it was ambiguous, so I am hopeful that between myself and Mr. Dingell, Mr. Stupak and Mr. Shimkus and others, we can introduce that bill very soon. But in the meantime we will continue to do, you know, aggressive investigative oversight. I want to commend Mr. Stupak and Mr. Dingell and Mr. Shimkus for their role in this effort, and I look forward to this hearing.

We have the National Governors downstairs in the big committee room on the SCHIP program, so several of us are going to be shuttling back and forth between food safety and SCHIP. They are both important hearings and they both deserve the committee's attention. I thank you, Mr. Chairman, for holding this hearing.

[The prepared statement of Hon. Joe Barton follows:]

STATEMENT OF HON. JOE BARTON

Thank you, Chairman Stupak. Let me note at the outset that I support the Committee's continued oversight of food safety and its efforts to gather new information on this issue. Nobody should have to worry whether dinner will make them sick, and my feeling is that most people will resent it if we let politics get between us

and good policy. So I look forward to working with you and writing bipartisan legislation to ensure that eating isn't going to become dangerous.

The various food-borne illness outbreaks, recalls, and import alerts over the past year raise questions on how to improve food safety even in the changing the realities of the modern marketplace. As we do so, we should not forget that it isn't the government, but the marketplace, that puts dinner on the table. Cutting-edge technologies and global connections have brought tremendous gains in variety and cost-savings to the American consumer. Like ancient Athens, our country draws the produce of the world into our markets, so that to the American, the fruits of other countries are as familiar a luxury as those of his own. We must preserve these benefits as we detect and eradicate any deficiencies in safety.

The cases we are looking at today raise legitimate concerns about failings in food safety oversight. Some of the health hazards are known, but surely not all, and many of the exact causes are not established.

Where we believe the facts and science support a safety problem, we should ask what changes, including legislative changes, could have prevented harm or at least reduced its probability. For example, if a company's microbiological testing misses traces of dangerous pathogens, but FDA's tests on the same products detects them, it seems plain that something at the company needs to change. But should the change include mandating particular testing methods for all companies? I don't know the answer yet, and I am not sure if one case study can answer that question.

The truth remains that in some of the cases we are examining today, the source of contamination simply isn't known yet, at least not by us. I hope that we get more answers from these companies today. And, I hope that these companies will explain what they plan to do to reduce the likelihood of future contamination in their products.

Our job is to find the right balance between federal regulation and industry responsibility. As overseers of safety, we want to protect the American public's health, but without strangling industry's productivity, creativity, and ability to supply Americans with the products they want to buy. I hope we begin to understand today where that balance lies and that our witnesses can offer their ideas on how to increase food safety.

No one here is going to tolerate lying, cheating, or wantonly violating any federal statute or good manufacturing practice, much less one that delivers food to be consumed on dinner tables or school lunchrooms. If laws or regulations were violated, the violators should be held accountable, and I can assure everybody here today that both Democrats and Republicans are of one mind about this. If laws or regulations are not being adequately enforced, those agencies should also be held accountable by us, and on a bipartisan basis.

Thank you, Mr. Chairman, and I look forward to listening to our witnesses' testimony.

Mr.STUPAK. Thank you, Mr. Barton.

And it is good to remind the members we will be moving back and forth. This week alone I think we have seven hearings for this committee, so it is going to be a busy week.

Mr. Doyle, for an opening statement, please.

Mr.DOYLE. Mr. Chairman, I am not going to make an opening statement, but I do just want to reiterate what our distinguished Chairman and ranking member both said.

We count on you folks to make sure this food supply is safe. In the Pittsburgh City School District we were recipients of some of this meat that had to be thrown away. It is a scary thought, that any parent or child, when we go and buy things in our stores should have to worry about whether or not this meat is going make us sick or kill us. Something obviously has to be done, and the industry needs to take this very, very seriously because I can assure you we take it very seriously.

Thank you, Mr. Chairman.

Mr.STUPAK. Thank you, Mr. Doyle. Mr. Burgess, for an opening statement, please.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr.BURGESS. Thank you, Mr. Chairman.

And to the interest of time I will keep my remarks brief. I think we have 10 witnesses that will testify before us today, and it is an important topic, and I am anxious to get to the matter at hand. This committee has aggressively pursued the issue of safety of the Nation's food supply. And I think we have made some progress in identifying some of the areas of the law where perhaps we have some inadequacies. Since our committee has jurisdiction over the Food and Drug Administration we have jurisdiction over roughly 80 percent of the food supply. In my opinion, especially for food imports, we should try to get the Food and Drug Administration standards, especially the equivalency standard up to a par with the United States Department of Agriculture, which has jurisdiction over the other 20 percent, specifically meat and poultry.

We have had a lot of hearings on this, and I think through those hearings, at least my opinion, that is where the danger primarily is. And I have actually introduced legislation that will address some of the safety problems with imported foods, specifically H.R. 3967. And we have rules in this country, but clearly the rules are not always followed, and they are not always enforced, but we have strict rules to keep our food safe. Other countries don't have the same rules, and I do not believe that we should accept food from other countries that do not certify that they abide by our standards.

While today we are discussing a specific incident at a specific plant history has proven that our meat is safe in this country because of the rules the United States Department of Agriculture has and the regulations that they have in place. Unfortunately, those rules this time were not enforced in California, but the rules were still there.

Mr. Chairman, as you know I am from Texas, and we like our beef. However, we also realize the dangers to consumers if beef products are not handled correctly. Our Nation has long recognized that our meat and poultry industry needed specific inspections and specific rules and regulations. Those inspections and rules and regulations must be enforced. There is simply no margin for error. There are no justifications to not enforce the rules. I am grateful the Humane Society brought this issue before us today, but I do have to wonder why they waited so long. The video was taped during the fall in the month of October, and they knew that the meat was going to school children. So why wait until February to release the video? Now, the Humane Society has friends on the hill. I count myself as one of those. I worked with the Humane Society on the issue of horse slaughter back in my home state of Texas, and working to affect the horse slaughter ban. So they have friends on the hill. Why wait until now to bring this to our attention? Their delay in no way absolves the companies involved or the United States Department of Agriculture for their part in this. But I certainly would like the Humane Society to address this issue.

Mr. Chairman, we must be thorough. We must be methodical as we continue to approach the issue of food safety. I look forward to continuing this important conversation today and working with the

leadership of this committee, and drafting legislation regarding the safety of the food supply, specifically the 80 percent that is under the jurisdiction of the Food and Drug Administration and as a consequence under the control of this committee.

I thank you for holding the hearing, and I will yield back the balance of my time.

Mr.STUPAK. Thank you, Mr. Burgess.

As to the video that you mentioned, we will have it right after the opening statements here. The video was given to law enforcement first. It took law enforcement some time to react. That is why the Humane Society did not put it out publicly. It was given to law enforcement so they could do their law enforcement work. I agree. Yes. And I don't think anything would have been done unless there had been the threat to release it publicly, because I think law enforcement may have fallen short here on this notification. We will have another hearing. I guarantee you. The Humane Society is here though.

Let us see. Opening statement, next to go to Mr. Murphy, please.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr.MURPHY. Thank you, Mr. Chairman.

And one of the things I realize in my time in Congress is how—what a mess it is, the Federal Food Safety Program. I believe there is over two, perhaps three, dozen laws and areas that make up the Federal Food Safety Program and no single agency oversees them all. This continues to be a nonsense gone fragmented system. And I believe we saw the situation where the Department of Agriculture and specs, open-faced meat sandwiches and frozen pepperoni pizzas, and the FDA inspects closed-faced sandwiches and cheese pizzas. We have had intensive hearings on that. One of the most challenging scientific things of our time. I say that tongue-in-cheek because sometimes it is ridiculous of how this system here in Washington works. And one of the things that I hope comes out of these hearings today is hearing from the witnesses of the how we can help make it better. That is critically important. Yes, we do have problems, and they are significant with 5,000 deaths and 325,000 hospitalizations a year of people who have food poisoning. I might add that also disturbing to me is we have two million hospitalizations a year and 90,000 deaths a year from people who pick up an illness in a hospital. Something that is certainly far more severe in terms of the number of fatalities we have, and also should demand the attention of this and other committees and the Engineering Commerce committee. But, nonetheless, in Pennsylvania where agriculture is our number one industry, where we have high quality companies in Pittsburgh, such as Heinz and Del Monte, we know the challenges are ongoing in preventing outbreaks in food borne illnesses. It has to be something that we all have to work at together. And I know there is a great deal of motivation for us all to point the fingers of blame. I want those fingers to point towards solutions, and not just be a time of roderick for us to be coming up with a tax. Every single statement made should be pointed in some direction of how we can make this system work better. The

public demands it. The public deserves it, and this committee needs to work on it. And I yield back.

Mr.STUPAK. Ms. DeGette, for an opening statement, please.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms.DEGETTE. Thank you, Mr. Chairman.

I am sure our witnesses have heard that we are all running from hearing to hearing. I think there are seven subcommittee hearings. And the Health Committee subcommittee hearing is also an issue I have been working on a lot. The SCHIP bill, so between food safety and SCHIP I want apologize to the witnesses for running back and forth today.

Over the last year this subcommittee has had five hearings examining the safety of our Nation's food supply. I am glad we are continuing this investigation, which has brought to light some serious inadequacies in our system, both in the public and private sectors. But sadly the hearings have turned out more questions than answers, and even more sadly, like just last week, there have been more outbreaks every time we have a hearing. What is absolutely maddening is that these incidents are preventable. In almost every case we can trace the serious threats to public health back to an agency that has been starved for funding or to a corporation with substantial agricultural or industrial practices.

I want to welcome the CEOs who are here with us today, and I am looking forward to hearing your testimony. I want to focus just a minute on ConAgra, because that is a major food producer nationwide, which has operations in my state of Colorado. Six years ago it was ConAgra which appeared before us to talk about one of the biggest recalls in history, after E. coli was found in its beef and so many people got sick. Last year they were before this committee talking about the peanut butter that was tainted with salmonella. Then it revealed that its popcorn contained chemicals that could make workers and consumers sick. And then this past fall citizens around the country were poisoned by ConAgra made pot pies containing salmonella. You can see how frustrating this is for us as representatives of the consumers, because the companies come before us, apologize profusely, and then they tell us about the new facilities they are installing or the money they are spending to make sure nothing like this happens again. So for example today, ConAgra is going to talk about its fantastic progress in ensuring the safety of Peter Pan peanut butter. Well, that is great news, but what about the pot pies? What about the next thing? I am sure the company has taken great pains at great expense to ensure the safety of the product, but what the next outbreak? And that is what we are worried about. With an organization this large that touches so many segments of the marketplace what can we do better to ensure these outbreaks do not happen in the future, rather than just coming in and apologizing but for the past? Now many of the companies before us today have been involved in massive recalls of tainted products. The members of this committee know that I have been introducing legislation for many years, H.R. 3484, that would grant the USDA and FDA mandatory recall authority. My

constituents are frankly shocked when they learn that right now these agencies do not have mandatory recall authority. They think they do, because they hear about the recalls. And they don't realize that the recalls are as a result of voluntary recalls by these companies. All of the recalls today, when they finally occurred, were issued voluntarily. And it is my contention that waiting on the company to make the decision is truly the fox guarding the hen house. ConAgra, for example, did not order a recall immediately upon learning of illnesses related to the pot pies. They issued a consumer advisory instead. It was only after days had passed, and even more people got sick, that the company decided it was in its financial best interest, in addition to the public interest, to recall the products. So this legislation, H.R. 3484, would correct the conflict of interest by allowing the USDA or FDA to order recalls as soon as it became clear that an outbreak has occurred, and it provides for the immediate notification of consumers and public health officials.

I want to thank you, Mr. Chairman, for continuing to work on these issues and I will pledge to be your partner, as always, as we move along. I yield back.

Mr.STUPAK. Thank you, Ms. DeGette.

Ms. Blackburn, for opening statement, please.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Ms.BLACKBURN. Thank you, Mr. Chairman, and I thank you for the hearing today and to all of our witnesses as everyone is saying.

We do have the SCHIP hearing that is going on downstairs, and we are back and forth. But we appreciate the hearing and the attention that is being put on this issue, because it is a high priority issue. It is not only one of public health and an issue that we are addressing on the public health front, but also the National security front.

I had a really interesting episode occur recently or a little occurrence. I was in my hometown in the grocery store strolling my buggy down the aisle, and someone was passing me and they said how do you know what to buy? How do you know what is safe anymore? And they kind of chuckled and rolled on. They had been watching the hearings. They were aware of what we were doing, but to me it points out something very, very important. There is a certain level of trust that the American public has of the products that you all produce. And they want to know with a certain degree of assurance that when they go to that grocery store and they take something off the shelf and put it into that buggy that it is safe. When they pull it out of the freezer compartment that it is safe. And when they cook it and serve it to their family, after having followed the directions, that everybody is going to be OK.

And my hope is that we can get through this. This is our fifth hearing as you have heard. It is something that we are tremendously concerned about, and we want to be certain that not only the FDA, but you all go from defense to offense. And how do we best accomplish that? I have been just amazed that only one percent of the 8.9 million shipments of imported food are inspected.

One percent. And we know from the USDA that we are expected to import a record 70 billion in agriculture products this year, which is double the nearly 36 billion purchased in '97, and that we have seen total food imports. The total imports have increased by 50 percent in the last five years, and it is frustrating to us that the FDA does not have a timeline for how they are going to change their practices to address this issue. So that something we are focused on and we are going to continue to work on.

I am not going to go through my full statement. You all have been very patient with us. We are going to be up and down. But I will tell you when we hear about recalls of pet foods and toothpaste and pizza products and baby formula, this is something that does get our attention. And we are going to seek accountability, greater accountability, through reform of the FDA system. We are looking for ways that we can make certain that the food coming into our product streams is something that is reliable and safe. They trust, the American consumers, trusts that we will do that. I am looking forward to making certain that everyone agrees to work together to make certain we reach this goal. Mr. Chairman, I thank you for the time, and I yield back.

Mr.STUPAK. Thank you. That concludes the opening statements of members of the subcommittee.

I'd like to call our first panel of witnesses to come forward.

[Witnesses sworn.]

Mr.STUPAK. Before we hear the witness's testimony I would like to show a brief video that was produced by the Humane Society as part of their undercover investigation of the Hallmark/Westland Corporation's slaughter house operation.

We invited Mr. Steve Mendell, the CEO of Hallmark/Westland to appear to day, but he refused the Committee's invitation. I do, however, plan to discuss this matter with the Chairman and with ranking members Barton and Shimkus as to our next step in compelling Mr. Mendell to appear before this committee to explain his company's behavior. Before we run the video I must caution viewers some parts of it is quite graphic. Kyle, run the video. You may want to dim those lights. I don't know if anyone can see it with these lights on. Then after the video we will start with opening statements.

[Video shown.]

Mr.STUPAK. That concludes the video. We will start with our 5-minute opening statement for our witnesses. You may submit a longer statement if you wish, for inclusion in the hearing record.

Mr. Greger, we will start with you, please. Dr. Greger.

STATEMENT OF MICHAEL GREGER, M.D., DIRECTOR OF PUBLIC HEALTH AND ANIMAL AGRICULTURE, THE HUMANE SOCIETY OF THE UNITED STATES

Dr.GREGER. Mr. Chairman, members of the subcommittee, thank you for this opportunity to testify about the——

Mr.STUPAK. Try pulling your mic up a little bit. Even up here it sounds like we are having a little bit—had a little bit of trouble here getting to project our voices. Go ahead.

Dr.GREGER. Thank you for allowing me to testify about the horrendous animal cruelty and food safety issues that we uncovered

in our extensive hidden camera investigation of this dairy cow slaughter plant in California.

My name is Michael Greger. I am a medical doctor and serve as director of Public Health and Animal Agriculture at The Humane Society of the United States. That video you saw was narrated from the perspective of our undercover investigator, who worked at the Hallmark packing plant for 6 weeks at the end of 2007 in both October and November. And personally witnessed and documented the egregious mistreatment of animals, particularly these downed cows to sick or injured to even stand or walk. And I trust you can appreciate the identity of this investigator must be kept confidential for his own safety and to not compromise the efficacy of his current investigative efforts and future efforts. It is critical to first point out that the agency did not cherry pick this plant. This plant was selected at random, and only during the course of the investigation did we learn that Westland was the number two beef supplier for the National School Lunch Program, that Westland was a USDA supplier of the year, and that this facility had been previously cited for mishandling animals, with allegations going back over a decade.

The blatant cruelties highlighted in the video are not isolated cases. They were daily happenings at this plant every day the worker was there. The horrific treatment of animals we documented is being downplayed as an aberration. Unconscionable, yet the work of just a handful of rogue employees. We don't think this is an accurate characterization. It has since come to light that this plant, Hallmark/Westland, has a long and well documented history of abusing downed cows. In fact, FSIS cited Westland in 2005 for mishandling animals and the local Pomona Valley Humane Society and SPCA had notified USDA multiple times about possible violations dating back to 1996. And this is not the only plant that has been documented to have downer cows going into the food supply. The USDA's own Office of the Inspector General chastised the agency in 2006 for violating its own downer policy. The OIG sampled 12 slaughter plants over a 10 month period, and found 29 downed cows going into the food supply. Again, violating the USDA's own interim final rule passed in 2004 after the first case of BSE was discovered in the United States.

Downed cattle are not only more likely to be infected with BSE, bovine spongiform encephalopathy or mad cow disease, but studies suggest they may also be more likely to harbor food borne pathogens, such as E. coli 0157H7, and salmonella. No surprise, perhaps, given the fact that many of these animals may be wallowing in their own waste. Despite the potential health risks, despite the legitimate animal welfare concerns, and despite their own Inspector General finding violations, the USDA in 2006, instead of strengthening the final downer ban rule they critically weakened it. Codifying a loophole into it that allowed some downed animals to continue to be slaughtered for human food. Currently inspection personnel are allowed to determine on a case-by-case basis the disposition of cattle that go down after passing antemortem inspection. And this loophole provides the incentive, the financial incentive, for what you just witnessed on that video. Workers trying every cruel tactic imaginable to get—to force downers up for the inspection,

knowing full well that should the animal then collapse down for good the loophole allows the inspector to pass downed animals. To pass that downed animal as USDA approved beef. If, on the other hand, downers could not go into the human food supply then there is no reason to prolong her misery. Even if a cow is down even for just what appears to an acute injury, like she breaks her leg, there may be an underlying disease that caused her to fall and break it. Indeed, at least three of the documented BSE cases in North America, were injured cattle. These infected cattle were identified as downed not due to illness, but due to injury. One, indeed, just broke a leg. Another slipped on ice. All right. And so the meat is safe, right? Because it is "just an injury," but it turned out it was more than just an injury. They had mad cow disease. A truly comprehensive ban on the use of any meat from downed animals in the human food supply is needed to protect food safety and animal welfare, and with vigorous enforcement, of course, to ensure compliance. USDA must rewrite its rules to close the current loophole and redirect resources to provide adequate oversight.

Finally, we urge Congress to enact swiftly two pieces of legislation that will help prevent such abuses from reoccurring. H.R. 661, the Downed Animal and Food Safety Protection Act by Representatives Ackerman and LaTourette, would implement a comprehensive ban on processing downed animals, which the USDA has so far failed to do. And H.R. 1726, the Farm Animal Stewardship Purchasing Act, by Representatives DeFazio and Shays should set basic animal welfare standards for producers who sell to the National School Lunch Program and other federal programs, including no downed animals.

Thank you, again, for this opportunity to testify about this important animal welfare and food safety issue.

[The prepared statement of Dr. Greger follows:]

THE HUMANE SOCIETY
OF THE UNITED STATES

Summary of testimony by Michael Greger, M.D., on behalf of the Humane Society of the United States (HSUS) to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, "Contaminated Food: Private Sector Accountability" hearing on February 26, 2008

Background: In fall 2007, an HSUS investigator accepted a job with Chino, CA's Hallmark/Westland plant. He drove cattle from trucks and pens into a chute that led to the kill floor. From his first day on the job, he witnessed blatant, commonplace cruelties inflicted on cattle by workers who ignored regulations meant to prevent the abusive torment of downers simply so they could get these crippled cows into the kill box, including: ramming downers with the blades of a forklift; jabbing them in the eyes; and torturing them with a high-pressure water hose to simulate drowning—all in attempts to force sick or injured animals to walk to slaughter. These were not isolated incidences, but heinous acts that happened routinely and were a part of the corporate culture.

Hallmark/Westland and USDA: From USDA's records, we found that in '07 Westland was the 2nd largest beef supplier to USDA's Commodity Procurement Branch, which purchases food for needy families, the elderly, and the National School Lunch Program, which distributed Westland beef to 43 states in the last two years. USDA named the plant '04-'05 "supplier of the year." A USDA veterinarian handling ante-mortem inspection was present only at 6:30 a.m. and 12.30 p.m.—predetermined times at which he approved for slaughter large groups of cattle if able to stand or walk.

USDA Knowledge of Illegal Animal Mistreatment: The abuses we documented are being downplayed as conducted by rogue employees, but there is a history of questionable behavior by the company. FSIS cited Westland in '05 for mishandling animals, and the Pomona Valley Humane Society and SPCA notified USDA three times about possible violations in '96 and '97. The USDA itself was not following its own stated policy of keeping downers out of the food supply. The USDA's Office of the Inspector General chastised USDA in '06 for its inconsistent and insufficient application of downer policies and regulations. The OIG sampled 12 plants in 10 months and found 29 downers were slaughtered for human food, and the audit noted the lack of documentation on the animals' fitness for consumption.

Human Health Concerns: Downed cattle may be at higher risk of contamination with conventional foodborne pathogens such as *E. coli* and *Salmonella*, and unconventional pathogens that cause mad cow disease and intestinal anthrax. In 2003, a USDA-funded study found downers more than three times *more likely* to harbor the potentially deadly *E. coli* O157:H7 strain than walking culled dairy cows. According to FDA: "Experience has shown that nonambulatory disabled cattle...are the population at greatest risk for harboring BSE." The FDA cites Swiss data showing a 49-58 times higher chance of finding BSE in downers than in cattle reported as BSE-suspect under passive surveillance. Of the 15 cases of BSE discovered in North America, 12 have reportedly been downers.

Unacceptable Loophole: The 2004 no-downer rule was weakened in July 2007, allowing inspection personnel to "determine on a case-by-case basis the disposition of cattle that become nonambulatory after they have passed antemortem inspection," which is an unrealistic, impossible expectation. Injury and illness are often interrelated, as we saw in at least three of the documented BSE cases in North America, in which downers were identified as nonambulatory due to injury, not illness.

Next Steps: We urge Congress to swiftly pass H.R. 661, the Downed Animal and Food Safety Protection Act, which would implement a comprehensive ban on processing downed animals, which the USDA has so far failed to do on its own, and H.R. 1726, the Farm Animal Stewardship Purchasing Act, which would set basic animal welfare standards for producers who sell food to the National School Lunch Program and other federal programs. USDA needs to revamp its inspection procedures, providing for more random ante-mortem checks and a greater presence of personnel in

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the handling areas. USDA should also require video cameras in the ante-mortem inspection area and allow for viewing of the tape by the inspectors and by independent 3rd parties.

Testimony by Michael Greger, M.D., on behalf of the Humane Society of the United States

February 26, 2008 Hearing: "Contaminated Food: Private Sector Accountability"

Subcommittee on Oversight and Investigations

House Committee on Energy and Commerce

Mr. Chairman and members of the subcommittee, thank you for the opportunity to testify about the horrendous animal cruelty and the many food safety gaps we exposed during a recent hidden-camera investigation of a dairy cow slaughter plant in southern California.

My name is Dr. Michael Greger and I serve as the Director of Public Health and Animal Agriculture for the Humane Society of the United States. You have just seen a video narrated from the perspective of our undercover investigator who worked at the Hallmark/Westland Meat Packing Company for approximately six weeks at the end of 2007. The investigator witnessed and documented egregious mistreatment of animals, particularly downed cows too sick or injured even to stand or walk.

Our investigator's own experiences and our other research findings have unveiled shortcomings with the U.S. Department of Agriculture's (USDA's) ante-mortem inspection program and weaknesses in the agency's policies on handling downer cattle.

The Investigation

In fall 2007, our investigator applied for a position with the Chino, California-based Hallmark Meat Packing Company, a federally inspected slaughter plant, which supplies carcasses to Westland Meat Company, which, in turn, processes the carcasses into ground beef. The companies are affiliated and essentially treated as one entity; they operate from the same building and share the same USDA registration number. From USDA's own records, we learned that in 2007 Westland was the second-largest supplier of beef to USDA's Agricultural Marketing Service (AMS). AMS purchases beef for distribution to needy families, the elderly, and also to schools through programs, including the National School Lunch Program, administered by the Food and Nutrition Service. Westland was named a USDA "supplier of the year" for the 2004-2005 academic year.

It is critical to point out that we did not do a broad risk assessment of a large number of plants and then conduct a more thorough examination of a high-risk facility. The plant was selected at random, and during the course of the investigation, we learned that Westland was the number-two beef supplier to the National School Lunch Program and to other USDA commodity distribution programs. We learned after the field portion of the investigation that Hallmark/Westland had previously been cited for mishandling animals.

The investigator's job at Hallmark was to help drive cattle from transport trucks and holding pens into a chute that led to the killing floor. He regularly worked grueling ten-hour days, five or six days a week. The job of getting tired, bewildered, and hungry cattle to move is challenging and made even more difficult when the animals are primarily end-of-production, or "spent," dairy cows, who are often sick, injured, and suffering.

Every day, he witnessed blatant and commonplace cruelties inflicted on animals by employees who purposefully ignored regulations meant to prevent the torment and abuse of downed animals simply so they could get these cattle who could not even walk into the kill box. He filmed workers ramming cows unable to stand with the blades of a forklift; jabbing them in the eyes; applying painful electrical shocks, often in sensitive areas; and torturing them with a high-pressure water hose to simulate drowning in attempts to force crippled animals to walk to slaughter.

It is important to note that these were not isolated incidences of mistreatment of downed cattle, but deliberate acts that happened routinely at the plant. They were part of the slaughter plant culture.

In fact, on the investigator's very first day of work, he saw a cow collapse on her way into the stunning box. After she was electrically shocked and still could not stand, she was shot in the head with a captive bolt gun to stun her and then dragged on her knees into slaughter.

A USDA inspector was only present in the live animal area twice daily at 6:30 a.m. and 12.30 p.m.—predetermined times at which he merely noted those animals who could not stand and then approved the remainder for slaughter. Let me emphasize the lack of rigor in the approval-for-slaughter process. The veterinarian did not make an animal-by-animal inspection, but simply took a look at large groups of animals as they passed by him, and if the animals could stand or walk, he would approve them. The inspector typically approved 350 animals for slaughter in the morning and then about 150 animals in the afternoon inspection.

The horrific treatment of animals we documented is being downplayed as an unconscionable aberration—the work of just a handful of rogue employees. We do not believe this is an accurate characterization. It has come to light that Hallmark/Westland has a long, documented history of abusing downed cattle. In fact, the Food Safety and Inspection Service (FSIS) cited Westland in 2005 for mishandling animals, and the local Pomona Valley Humane Society and SPCA notified USDA three times about possible violations in 1996 and 1997. In 1996, the Pomona Valley Humane Society wrote a letter to Hallmark stating: "We have had numerous incidents with your facility in the past involving downer animals and loose animals creating public safety issues." The USDA was copied on that letter. Either management provided instructions to get the downers moving or was asleep at the wheel and let employees run wild—in either case, it's an indictment of management.

In terms of the larger picture of USDA oversight, we also know that slaughtering nonambulatory cattle was not isolated to this plant. The USDA's own Office of the Inspector General (OIG) chastised the agency in 2006 for its inconsistent application of downer policies and regulations after observing the processing of downed cattle. The use of a forklift was observed to move downed animals to the slaughter area. The OIG sampled 12 slaughter plants in 10 months and found that 29 downed cattle were slaughtered for human food, and the audit noted the lack of documentation on the animals' fitness for consumption. This practice contravened the operational rule, published in January 2004, that banned any slaughter of downed cattle and was adopted in the wake of the first positive finding of bovine spongiform encephalopathy (BSE) in the United States in Washington State.

The investigation by the Humane Society of the United States[1] is not the only one to uncover this scandalous and dangerous treatment of downed cattle, but it is the most recent. Others[2-4] have also documented abuses to crippled cattle in efforts to move them at slaughter facilities.

As a result of our effort, the FSIS, citing "egregious violations of humane handling regulations," suspended inspection at Hallmark and the Agricultural Marketing Service temporarily suspended the slaughter plant's vendor status, making it ineligible to sell beef to the government,[5] and the company is now responsible for

the largest beef recall in U.S. history.[6] At least 47 states had directly or indirectly received shipments of recalled beef purchased by the USDA. The San Bernardino County District Attorney has charged a Hallmark supervisor with five felony counts under California's anti-cruelty statute and three misdemeanor counts alleging the use of a mechanical device to move nonambulatory cattle, and a second worker has been charged with three misdemeanors involving downers. The investigative findings of downed cattle mistreatment and allegations of nonambulatory animals being slaughtered for human consumption also prompted congressional reaction,[7] led school districts to pull beef from their menus,[8] and purportedly led to questioning of the reliability of the USDA inspection process.[9] But, despite all of this, sick and injured cattle can and likely will still be slaughtered and put into the American food supply unless fundamental changes are implemented to protect animal welfare and protect human health and that of the Nation's most vulnerable citizens.

Human Health Risks Associated with the Slaughter of Downed Cattle

Aside from the serious welfare concerns of such treatment of downed animals, this practice raises food safety issues, as some studies have shown that nonambulatory cattle may suffer from higher rates of foodborne pathogens.[10]

Texas A&M University researchers were among the first to alert the medical community of the potential for downed cattle to present a vehicle to contaminate the human food supply with bacterial pathogens. They studied 30 downed cattle who had no outward signs of illness, except for inability to rise, and had all passed antemortem inspection. Even though these nonambulatory animals appeared otherwise healthy, when the researchers took bacterial cultures, they found cows infected with *Salmonella* and *E. coli*. The researchers concluded: "Results of this study of 30 cattle indicate that pathogens may be circulating in the blood of some recumbent cattle at the time of slaughter."[11] Commenting on areas of concern, the scientists noted:

> It should be remembered that much of the meat from recumbent cattle goes into the production of ground beef, which, because of the grinding process and extra time it spends at a temperature higher than the whole carcasses, usually attains a high bacterial cell count per gram by the time processing is finished. Contaminated meat used to make ground beef would also contaminate subsequent clean meat exposed to common machinery (eg, grinders) and, thus, would increase the danger of contamination.[11]

This research shows that even when downed animals appear otherwise healthy, they may be harboring dangerous pathogens.

The majority of nonambulatory cattle are dairy cows.[10] Virtually all dairy cows are ultimately slaughtered for human consumption in the United States.[12] Annually, 6 million culled dairy cows enter the food chain as ground beef,[13] accounting for at least 17% of the ground beef produced in the United States.[12] Since the muscles of dairy cows have a lower fat content, they are commonly used in producing the more expensive "lean" hamburger.[14]

According to a 2003 review, downed dairy cattle "may harbor greater numbers of pathogens, and their slaughter may increase spread of pathogens at the slaughter establishment."[15] In *Meat & Poultry*, research is cited to explain why nonambulatory cattle tend to have higher levels of bacteria on their carcasses: "Lame animals spend more time lying down, which increases the likelihood they will be contaminated with fecal matter."[16] In addition to the potential for contamination of the meat with fecal pathogens, when dairy cows are slaughtered, "[k]nives, carcasses and the hands of personnel may be contaminated by contents of the mammary gland when this is removed from the cow during processing."[12] Intramammary infections (mastitis) affect up to nearly two-thirds of cows in U.S. dairy herds[17] and are one of the most common reasons dairy cows are sent to slaughter.[12] Inappropriate excision of the udder during the slaughter process can contaminate the rest of the carcass with milk that could contain *Listeria* and other milk-borne pathogens. A 1997 review of the microbiological hazards of eating meat from culled dairy cows concluded: "In the USA, dairy cattle are raised and managed with increasing intensification, and this intensification may promote the

maintenance of a variety of micro-organisms which could be pathogenic to humans through food."[12]

E. coli O157:H7

In 2003, a study funded by the USDA was published that investigated the "potential impact to human health that may occur following consumption of meat derived from downer dairy cattle" by measuring infection rates of one of the most virulent foodborne pathogens, *E. coli* O157:H7. The investigators found that downed cows were 3.3 times more likely to harbor the potentially deadly *E. coli* strain than walking culled dairy cows. The researchers concluded that "downer dairy cattle harboring *E. coli* O157:H7 at slaughter may be an important source of contamination and may contribute to the health risk associated with ground beef."[18] The results of this study led USDA Microbial Food Safety Research Unit Research Leader John B. Luchansky to question whether, based on *E. coli* alone, nonambulatory cattle should be excluded from the U.S. meat supply.[19]

E. coli O157:H7 infects tens of thousands of Americans every year, causes dozens of deaths,[20] and may be the leading cause of acute kidney failure in previously healthy U.S. children.[21] Speculatively blamed in part on the increasing intensification of dairy farming,[22] prevalence rates in U.S. dairy herds have ranged up to 100%.[23] Quoting USDA researcher Caitriona Byrne and colleagues: "Due to the ubiquity of *E. coli* O157:H7 among cattle, as well as its low infective dose and

the severity of the resistant illness in humans, effective control of the pathogen may be possible only by eliminating this microorganism at its source rather than by relying on proper food handling and cooking thereafter."[18]

A 2005 review in the *Journal of Dairy Science* likewise concentrated on the risk of contracting virulent strains of *E. coli* from eating ground beef from dairy cows that may be tainted with fecal material. These toxin-producing strains can cause hemorrhagic colitis and progress to kidney failure, coma, and death, particularly in young children.[21] Dairy cattle "enter the food chain as ground beef," the review reports, and "[a]s a result, downer dairy cows harboring STEC [Shiga toxin-producing *E. coli*] at slaughter can be a health risk to humans."[13] Meat from diseased and disabled cattle has also been implicated in a similar life-threatening disease in dogs.[22]

Salmonella

Salmonella infection hospitalizes thousands of Americans every year, kills hundreds, and can lead to chronic conditions such as arthritis, bone infections, cardiac inflammation, and neurological disorders.[24] According to the Centers for Disease Control and Prevention, *Salmonella* strains in the United States are growing resistant to nine different antibiotics.[25] One strain, known as *Salmonella* Newport MDR-AmpC, is even growing resistant to ceftriaxone, a powerful antibiotic vital for combating serious infections in children.[25]

Multiple outbreaks of this new multidrug-resistant *Salmonella* strain have been tied to dairy farms,[26] ground beef made from dairy cows,[27] and dairy products.[28] Investigating one deadly outbreak of antibiotic-resistant *Salmonella* involving hundreds of people, California public health officials traced the cases back to meat from infected dairy cows slaughtered for hamburger. In their report published in the *New England Journal of Medicine*, they were able to correlate risk of contamination with the slaughter plants that received the most moribund and dead cattle. The researchers noted: "Stressed animals are more likely to shed *Salmonella* in large numbers."[14]

In addition to the immunosuppressive effect of stress, nonambulatory animals may also be more likely to shed pathogenic bacteria, "[s]ince animals going to slaughter are generally in a temporary state of starvation, and it is known that starvation causes *E. coli* and *Salmonella* to proliferate" due to changes that occur in the animal's rumen. By the time most cattle are slaughtered, they have been starved for variable periods of time, in part because empty rumena are easier to eviscerate.[22] This may be particularly relevant to downed cattle populations who may be left to starve for extended periods before they are finally slaughtered.

Carolyn Stull of the University of California-Davis School of Veterinary Medicine has studied *Salmonella* infection in downed cows and reported her results at a 2004 American Meat Institute conference. Her team sampled 50 downed cows and found

7 to be infected with *Salmonella*. Despite infection, however, at least five out of the seven infected cows, including at least one cow who was septicemic, were known to have passed USDA antemortem inspection for human consumption.[29] Another pilot study identified 6 out of 20 nonambulatory cattle sent for slaughter to be fecal shedders of *Salmonella*.[30]

Anthrax

Anthrax is a farm animal disease that can infect, though very rarely, the human meat supply.[31] In 2000, 32 farms were quarantined for anthrax in the United States.[32] That summer, at least five people were exposed to meat "highly contaminated" with anthrax from a downed cow who was approved for slaughter and human consumption. These cases were reported by the Centers for Disease Control and Prevention as "Human Ingestion of *Bacillus Anthracis*-Contaminated Meat."[33] Had a ban on the slaughter of downed cattle been in effect, these people may have been spared. Subsequently, a family stricken with gastrointestinal, oropharyngeal, and meningeal anthrax tied to the consumption of a sick sheep was reported,[34] suggesting it may be prudent to exclude all nonambulatory animals—not just cattle—from the human food supply.

Frank Garry, the coordinator for the Integrated Livestock Management Program in the College of Veterinary Medicine and Biomedical Sciences at Colorado State

University, reportedly suggests that the slaughter of nonambulatory farm animals may present a threat to national security:

> The threat of bioterrorism adds one more reason to end the use of nonambulatory animals in human food. An animal that is unable to walk because of illness should probably not be processed for human food consumption, regardless of whether the animal was intentionally or unintentionally contaminated. As long as the USDA continues to slaughter diseased livestock, it is possible that a bioterrorist attack could make people very sick and undermine confidence in American agriculture.[35]

Culled dairy cows may present particularly vulnerable agroterrorist targets as they are slaughtered and ground into hamburger. "Given that only a single infected carcass can contaminate a large lot of ground beef," wrote USDA researchers in a 1996 review, "it is possible that, whereas in the past an infected animal would produce only a small number of cases, such an animal could now cause a large, widespread outbreak."[22] According to Robert Tauxe, Chief of the Foodborne and Diarrheal Diseases Branch of the Centers for Disease Control and Prevention, each burger may reportedly be made from the flesh of hundreds or even thousands of different cows.[36] One mathematical model suggests that a single downed cow infected with a pathogen such as *E. coli* O157:H7 could theoretically contaminate more than 100,000 hamburgers with an infectious dose.[22]

Bovine Spongiform Encephalopathy

Bovine spongiform encephalopathy is a transmissible spongiform encephalopathy (TSE) of cattle that may manifest with behavioral symptoms, earning the disease its colloquial name "mad cow disease." The rendering of sheep infected with an ovine spongiform encephalopathy (known as scrapie) into cattle feed may have led to the emergence of BSE.[37] In modern animal agriculture, protein concentrates, or "meat and bone meal"—terms that encompass "trimmings that originate on the killing floor, inedible parts and organs, cleaned entrails, fetuses"[38]—are fed to dairy cows, for example, to improve milk production.[39] According to the World Health Organization, nearly 10 million metric tons of slaughter plant waste is fed to farm animals every year.[40]

Although the first case of BSE was documented in the United Kingdom in 1986, there reportedly exists "very sound" evidence that a rare form of the disease was already circulating in the United States.[41] One year before BSE was initially reported in Britain, Richard Marsh, chair of the Department of Veterinary Science at the University of Wisconsin-Madison, was alerting dairy producers of the possibility that a "previously unrecognized scrapie-like disease in cattle" existed in the United States[42]—a concern borne out of investigations of sick mink.

Mink have proven to be sentinel animals, like canaries in coal mines. They were reportedly the first, for example, to show toxicity from the vaginal cancer-causing

synthetic estrogen diethylstilbestrol (DES) and the industrial carcinogens polychlorinated biphenyls (PCBs).[43] Since 1960, there have been four outbreaks of mink spongiform encephalopathy known as transmissible mink encephalopathy (TME) on U.S. fur farms.[44] This was perplexing, as researchers had been unable to orally infect mink with scrapie-infected sheep brains.[45]

A clue to the origin of the disease came in 1985, when TME devastated a population of farmed mink in Wisconsin who had reportedly not been fed any sheep.[46] The meat portion of their diet evidently consisted almost exclusively of downed dairy cows.[47] Marsh hypothesized that there was a form of BSE in the United States that manifested itself as more of a "downer" cow disease than a "mad" cow disease.[45]

Mink were found to be experimentally susceptible to BSE; when mink were fed BSE-infected brains from British cattle, they died from a spongiform encephalopathy.[44] The disease was experimentally spread from mink to cows and from cows back to mink.[47] The critical experiments, though, involved inoculating the brains of U.S. sheep infected with scrapie into U.S. cattle.[48] In England, scrapie-infected cows go "mad," twitching and kicking. But, in the United States, the "real surprise,"[41] as Marsh recounted, was that scrapie-infected cattle instead developed difficulty in rising and terminal recumbancy[49] like downed cattle do.[48] "The signs that these cattle showed were not the widely recognized signs of BSE—not signs of mad cow disease," Marsh reportedly said. "What they showed was what you might

expect from a downer cow."[50] Scientists have identified multiple strains of scrapie.[51] Marsh posited that one of the U.S. strains may have jumped to cattle, creating a form of BSE native to the United States.[43] Said Marsh to a reporter: "That's the only conclusion you can draw."[41]

Every year in the United States, estimates range from 195,000[52] to 1.8 million[53] cattle who collapse for a variety of metabolic, infectious, toxic, and/or musculoskeletal reasons and are too sick or injured to rise.[10] Extrapolating from the proportion of nonambulatory cattle found in European[54] and U.S.[10] surveys, the number of nonambulatory cattle in the United States may be on the order of 500,000 a year. A governmental survey of dairy producers across 21 states reportedly found that 78.2% of dairy operations had nonambulatory cows during 2004.[55] Though these animals may not have been fit enough to stand, a limited investigation of USDA slaughter plant records between January 1999 and June 2001 showed that most were still ruled fit for human consumption.[56]

Based on findings in Europe[54] and the speculative evidence of a rare form of mad cow disease striking downed cows for decades in the United States,[57] nonambulatory cattle should considered to be a particularly high-risk population. According to the Food and Drug Association (FDA): "Experience has shown that nonambulatory disabled cattle...are the population at greatest risk for harboring BSE."[58] The FDA cites Swiss data showing a 49-58 times higher chance of finding BSE in downed cattle than in cattle reported to veterinary authorities as BSE-

suspect under passive surveillance.[59] Indeed, 12 of the 15 BSE-infected cattle discovered in North America by February 1, 2008, have reportedly been nonambulatory.[60-71]

Though the riskiest tissues—the brains, eyes, and spinal cords—of most cattle are now excluded from most food items in the United States,[72] there may be contamination of muscle meat via aerolization of the spinal cord during carcass splitting.[73] Significant amounts of central nervous system debris found accumulating in the splitting saws used to halve the carcasses may have the potential to then transfer contagion from one carcass to the next.[74] Although, technically, processors are instructed to knife-trim "material grossly identifiable as brain material, spinal cord, or fluid from punctured eyes,"[75] researchers have reported finding nervous tissue contaminating muscle in a commercial slaughter plant.[76] Contamination of meat derived from cattle cheeks with brain tissue can also occur if the cheek meat is not removed before the skull is fragmented or split.[77]

Captive bolt stunning, the predominant method used to render cattle insensible before exsanguination,[78] may blow a shower of embolic brain tissue into the animals' bloodstream. In one experiment, a biological marker applied onto a stunner bolt was later detected within the muscle meat of the stunned animal. The researchers concluded:

> This study demonstrates that material present in...the CNS [central nervous system] of cattle during commercial captive bolt stunning may become widely dispersed across the many animate and inanimate elements of the slaughter-dressing environment and within derived carcasses including meat entering the human food chain.[79]

Captive bolt stunning may also lead to ejection of brain tissue into the abattoir from the hole made by the captive bolt onto slaughter plant equipment, as well as the hands and aprons of workers removing the animals' heads.[76] A follow-up study published 2004 in the *Journal of Food Protection* determined that "this method of slaughter of an animal infected with bovine spongiform encephalopathy would be likely to contaminate edible parts of the carcass with infective material."[80] Texas A&M University researchers found bodily brain fragments as large as 14 cm (5.5 in). The researchers concluded that it was likely that BSE pathogens could potentially be "found throughout the bodies of animals stunned for slaughter."[81]

Despite the potential for CNS contamination and the fact that peripheral nerves[82] and blood[83] found in all muscles may carry infection, the USDA[84] and the National Cattlemen's Beef Association[85] have attempted to assure consumers that beef is safe to eat, arguing that the infectious agent is not found in muscle meat. However, Stanley Prusiner, the director of the Institute for Neurodegenerative Diseases at the University of California, San Francisco, and winner of the Nobel Prize in Medicine for his discovery of prions, the cause of the BSE and other TSEs, proved in mice

that muscle cells themselves were capable of forming the potentially infectious agent.[86] "I found prions in the hind limb muscles of mice," Prusiner stated, "at a level approximately 100,000-fold higher than that found in blood."[83] Prusiner reportedly described the studies relied upon by the Cattlemen's Association as "extraordinarily inadequate,"[87] and follow-up studies in Germany confirmed his findings, showing that animals who are orally infected may indeed end up with prion contamination throughout the muscles of their bodies.[88]

Although the risk of contracting BSE appears vanishingly small in the United States given how few cattle have tested positive, the neurodegenerative disease it can cause in the consumers of contaminated beef is likely invariably fatal. Because cooking temperatures do not adequately destroy prions, the onus of responsibility must rest with the beef industry or, if unable or unwilling to police itself, the federal government, to ensure infected cattle are not slaughtered for human consumption. There is evidence that the infectious proteins that cause BSE can survive incineration[89] at temperatures hot enough to melt lead.[90] In response to a question from Cornell University's Food Science Department asking what food preparation methods could eliminate the risk of contracting BSE, then National Institutes of Health Laboratory of Central Nervous System Studies chief Joseph Gibbs remarked tongue-in-cheek that one of the only ways to ensure a BSE-free burger would be to marinate it in a concentrated alkali such as Drain-O™.[91]

Nonambulatory Cattle Slaughter Ban Loophole

Within weeks of the discovery of the first case of BSE in the United States in 2003, the USDA released a package of regulations designed to protect the nation's food supply.[92]

The USDA's downed cattle regulations published January 12, 2004, instructed USDA veterinary inspectors to condemn any cattle arriving at slaughter plants "nonambulatory disabled," defined as any cattle who "cannot rise from a recumbent position or…cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions."[78] Since BSE can result in an animal going down either directly, because of brain damage, or indirectly, by predisposing an animal to injury, these downed cows were to be euthanized rather than slaughtered for human consumption.

The same day that the regulations were published, however, the USDA issued Notice 5-04, instructing inspecting veterinarians how to carry out the regulations. In contrast to both the public claims by the USDA and the interim rule itself, the agency instructed inspectors to allow downed cows to be slaughtered for human consumption if they initially appeared otherwise healthy but went down within the slaughter plant itself due to an acute injury (e.g., if the animal falls and breaks a leg).[93] This loophole is cavalier, since underlying disease in general and BSE in

particular may make an animal disoriented, weak, or uncoordinated and thereby predispose an animal to an injury sustained in a fall.

Now retired after 20 years with the USDA, Linda Detwiler was the senior staff veterinarian in charge of the USDA BSE surveillance program. In written comments submitted to the USDA, she strongly opposed any attempt to weaken the definition of "downer" to exclude those downed presumably solely from injury. "I urge the USDA to not alter this definition," she wrote, "and to continue to prohibit for human food any bovine which cannot walk to the 'knock box' [slaughter area] regardless of reason."[94]

Because illness may predispose an animal to injury, Detwiler argued that the underlying cause of the nonambulatory condition may be impossible to ascertain. In other words, a broken leg might just be a symptom of a more serious problem, such as BSE. A 2003 review of the nonambulatory cattle problem concluded: "It should always be considered that two or more conditions may present simultaneously in a downer cow...."[95] Bovine veterinarian Jim Reynolds of the University of California's School of Veterinary Medicine reportedly agrees: "It is very, very difficult for a veterinarian to differentiate the many reasons a cow may be non-ambulatory."[96] At least three of the documented cases of BSE in North America were identified as downers due to injury, not illness,[60,62,64] underscoring how difficult it is for inspectors to reliably determine which nonambulatory animals may be "safe."

The first case of BSE discovered in Canada was thought to be "suffering from a broken leg."[60] The first U.S. BSE case similarly did not seem to display any BSE symptoms—the cow was reported down due to a birthing injury that reportedly interfered with her ability to walk.[62] She was seemingly picked at random as one of perhaps less than 1% of the downed cattle tested for mad cow disease in the United States up until that time.[97] Similarly, a third North American case was suspected of injury rather than disease. The farmer reportedly "didn't suspect anything was seriously wrong when one of his cows slipped on the ice and hurt itself...."[64]

As discussed above, in 2006, the USDA Office of the Inspector General criticized the agency for its inconsistent application of policies and regulations related to downed animals after observing nonambulatory cattle processed at two slaughter plants. In a review of 12 slaughter plants observed over the period June 17, 2004, to April 12, 2005, the OIG found that 29 downed cattle were slaughtered for human food. They "observed use of a forklift and a rail above the pens to transport nonambulatory cattle to the slaughter area." The audit noted the lack of documentation on the animals' fitness for human consumption.[98] Nevertheless, USDA's on-the-ground operational conduct—documented in the OIE report—was codified in 2007 by amending the final rule to allow inspection personnel to "determine on a case-by-case basis the disposition of cattle that become nonambulatory after they have passed antemortem inspection...."[99]

Next Steps

Nonambulatory cattle should be considered veterinary medical emergencies because they are precisely that.[10]

Given the serious animal welfare concerns and the many health risks associated with slaughtering downed animals for human consumption, the loophole in current downer protocol that was codified in 2007 and is wide enough for rampant cruelty to animals and foodborne pathogens to pass through, must be closed. The current protocol that allows inspection personnel to "determine on a case-by-case basis the disposition of cattle that become nonambulatory after they have passed antemortem inspection" is unrealistic and unworkable, and places an impossible expectation on the inspector.

Determining why an animal is down is challenging if not impossible for inspectors because injury and illness are often interrelated, as we saw in at least three of the documented BSE cases in North America in which downers were identified as nonambulatory due to injury, not illness.

As we documented during our investigation at Hallmark, nonambulatory cattle are being abused and are being slaughtered for human consumption. USDA cannot publicly boast about its comprehensive no-downer policy while it continues to allow some downer cattle to be processed for human food. Indeed, for years, the

Agency has spoken about its comprehensive no-downer policy but circumvented it behind-the-scenes with the loophole that permits slaughter of some cows unable to walk. USDA has failed to follow its official interim policy published on January 12, 2004, which specified that all downer cattle would be excluded from the human food supply, regardless of the reason the animal was nonambulatory and regardless of whether the animal went down before or after antemortem inspection. In July 2007, USDA finally made permanent its so-called "ban" on slaughtering downer cattle, but in its announcement, the agency admitted that some downer cattle have been, and will continue to be, processed for human food.

USDA's lax enforcement of the downer rules is simply unacceptable. As documented by our investigation, inspectors may only conduct cursory observations, coming to check on animals at most twice a day and disregarding their condition for the remaining hours.

An unequivocal, truly comprehensive ban on the slaughter of downed animals for human consumption—with vigorous enforcement to ensure compliance—is needed to protect food safety and animal welfare. USDA must rewrite its rules to close the current loophole and redirect resources to provide adequate oversight. A highly visible and vigorously enforced total no-downer rule would yield immediate benefits for schoolchildren and other consumers. For the animals themselves, removing current incentives that encourage workers to try every cruel tactic imaginable to move downers to the kill box would alleviate suffering—if crippled

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animals cannot be sold for food, slaughter plants have no reason to prolong their misery to try to get them through the slaughter process.

We urge Congress to swiftly pass two pieces of legislation that will help prevent such abuses from recurring: H.R. 661, the Downed Animal and Food Safety Protection Act, by Reps. Gary Ackerman and Steve LaTourette, would implement a comprehensive ban on processing downed animals, which the USDA has so far failed to do on its own. And H.R. 1726, the Farm Animal Stewardship Purchasing Act, by Reps. Peter DeFazio and Christopher Shays, would set basic animal welfare standards for producers who sell food to the National School Lunch Program and other federal programs.

We also encourage your committee to recognize that this case demonstrates some deep and systemic flaws in USDA's oversight of slaughter plants. I understand that USDA is sometimes held up as the "gold standard," particularly when compared with FDA's food safety oversight. But USDA has an inherent conflict of interest, with its prime mission being to promote agriculture, a mission that seems too often to trump its other responsibilities.

Thank you for the opportunity to testify here today on this important food safety and animal welfare issue.

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Praise for

Bird Flu: A Virus of Our Own Hatching

by Michael Greger, M.D.
Director of Public Health and Animal Agriculture
The Humane Society of the United States

"The book is timely, well written, and very comprehensive from any reader's perspective. It also can help people understand the urgency of a possible avian flu pandemic as it now exists, and how it could affect the health and well-being of people everywhere."
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"Your contribution to research is commendable...."
– **Colonel George W. Korch, Jr.**, Commander of the U.S. Army Medical Research Institute of Infectious Diseases

"I just finished reading it and found it extremely interesting. It is a perfect sequel to Gina Kolata's Flu and perhaps even more appropriately, John Barry's The Great Influenza. I sincerely hope your book generates a lot of press. I plan to let my public health colleagues know that the book will be available online at BirdFluBook.org."
— **Linda Tollefson**, Food and Drug Administration (FDA) Assistant Commissioner for Science and former Deputy Director of Center for Veterinary Medicine

Mr.STUPAK. Thank you.
Mr. Williams, opening statement, please.

STATEMENT OF JOHN A. WILLIAMS, EXECUTOR DIRECTOR, SOUTHERN SHRIMP ALLIANCE

Mr.WILLIAMS. Good morning. My name is John A. Williams, and I am here today both as someone with 30 years of experience in the shrimp industry and as Executive Director of the Southern Shrimp Alliance.

I operate a small business in Tarpon Springs, Florida, and I am proud to have the privilege of representing the other small business men and women in the shrimp industry. Thousands of other small businesses of men and women in the shrimp industry throughout the Gulf of Mexico and the south Atlantic.

Mr.STUPAK. Would you pull that mic up a little bit closer, please, sir?

Mr.WILLIAMS. Thanks. I appreciate the opportunity to testify on the FDA's failure to protect Americans from harmful seafood imports. I ask the committee to refer to my written comments for more detail on the urgent need for meaningful FDA reform.

There can be no denying that the FDA is broken. The essence of FDA's approach to imported food safety is to accept unverified representations of importers who have repeatedly disregarded the safety of American consumers. We know and the FDA knows that aquaculture in much of the developing world has led to the introduction of harmful contaminants into our imported seafood. Imported foreign raised shrimp are often produced with minimal quality control in crowded ponds filled with feces, banned antibiotics and toxic chemicals. And yet, the FDA's only check on self-serving representations is the inspection of one percent of seafood imports.

The FDA's failure to prevent importation of massive amounts of contaminated shrimp has a number of negative effects on our market. In addition to putting consumers at risk, contaminated shrimp imports depress demand for all shrimp when consumers fail to distinguish between safe and unsafe sources of shrimp. Shrimp buyers know that shrimp sources from farms in countries with lax controls are likely to be contaminated and, therefore, offer lower prices.

In addition, the simple fact that large amounts of shrimp enter the U.S. market that should not have been allowed to enter further depresses prices for all shrimp. The combination of stringent imported food safety regimes and other major importing markets and lax enforcement of U.S. law encourages the diversion of contaminated seafood to the United States. Canada, Japan and the European Union all do significantly more to protect consumers than the FDA to safeguard the American public. As a result our Nation has become a dumping ground for rejected and inferior seafood products that could not be exported to other countries.

For example, when the EU imposed a complete ban of shrimp from China in 2002 because of illegal antibiotic use, Chinese shrimp imports to the United States shot up 30 percent in one year, adding millions of additional pounds of shrimp to this market. And the same thing happened when the EU decertified Pakistani seafood products in April of 2007. In just 2 months, Pakistani shrimp to the U.S. jumped from 0 to 165,000 pounds. Now we are

facing the same problem with Vietnam. While the EU, Japan and Canada all have recently taken action against Vietnamese shrimp for illegal antibiotic use the FDA has done nothing. The FDA has sufficient evidence of the hazards of farm raised seafood from Vietnam, both from its own investigation and as we have been told by reliable sources from direct admission by Vietnamese authorities, of the widespread use of banned substances in the production of farm raised seafood. And for some of those substances the FDA apparently has no testing protocol to detect them. Concerns about the FDA's inability to assure the safety of the imported seafood has risen to the point that states have been doing their own testing of seafood imports. And these states have repeatedly found harmful banned substances in the imported seafood they test—seafood allowed by the FDA to enter this country. While we are pleased that state governments have attempted to step into the breech, the burden of ensuring that imported seafood is safe to consume should not be forced upon them. There is no substitute for a strong federal food safety system. Unfortunately, the FDA appears to take action only when facing a crisis or public outrage.

We respectfully suggest that this committee should be outraged. We have prepared a series of proposals for legislative changes to improve the safety of imported seafood. These proposals are discussed in detail in my written testimony, but I will provide a couple of examples here.

The FDA should require, as a condition of importation, that the country of origin of an imported seafood product administer a system of food safety that is equivalent to that of the United States. Also, the FDA should take note of the detection by other major importing countries of contaminants in food so that the FDA can focus its enforcement effort. For the health of our consumers, for the integrity of our Nation's food supply I ask you, members of this committee, to enact meaningful FDA reform. The FDA has promised before that it can change on its own, but the evidence demonstrates just how dangerous the FDA's broken promises have become. Thank you.

[The prepared statement of Mr. Williams follows:]

Testimony of

John Williams

Executive Director of the Southern Shrimp Alliance

before the

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives

February 26, 2008

My name is John Williams and I am here today both as the Executive Director of the Southern Shrimp Alliance ("SSA")[1] and as someone with 30 years of experience in the shrimp industry. After starting as a deck hand working aboard shrimp boats in North Carolina, I now operate a small business in Tarpon Springs, Florida and I am proud to have the privilege of representing thousands of other small businessmen and women in the shrimp industry throughout the Gulf of Mexico and South Atlantic.

We are proud that wild-caught American shrimp is premium-quality seafood caught by American shrimpers and delivered fresh to local docks. Wild-caught American shrimp mature at a natural pace, flourishing in nutrient-rich marshes and estuaries before naturally migrating to the Atlantic Ocean or Gulf of Mexico. Because they are grown naturally in oceans, there is no need nor is there any economic incentive to use antibiotics or pesticides on wild-caught American shrimp. People who eat wild-caught American shrimp can be assured that their shrimp meets the standards for U.S. quality and safety. The same cannot be said for imported shrimp.

I appreciate the opportunity to testify on the U.S. Food and Drug Administration's ("FDA") failure to protect Americans from harmful seafood imports. There can be no denying that the FDA is broken. The essence of the FDA's approach to imported food safety is to accept unverified representations of importers who have repeatedly disregarded the safety of American consumers. The FDA does not require foreign government or foreign producer equivalence as a condition of entry into the United States. In the absence of equivalence agreements or certifications, the FDA relies solely on its very limited testing of imported seafood to identify food safety violations. But because the frequency of FDA testing is not mandated by law, FDA inspection rates have hovered at 1 percent since 2002. In consequence, the FDA is effectively allowing exporters to self-certify their compliance with U.S. food safety standards.

We know, and the FDA knows, that aquaculture in much of the developing world has led to the introduction of harmful contaminants into our imported seafood. Imported farm-raised shrimp are often produced with minimal quality control, in crowded ponds

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[1] For additional information about the SSA's food safety efforts and other issues, please visit http://www.shrimpalliance.com/.

filled with feces, banned antibiotics, and toxic chemicals.[2] And yet, the FDA's only check on self-serving representations from those who profit on imported seafood is to inspect a tiny amount of these imports. Furthermore, the FDA typically tests for a small number of the long list of illegal additives and contaminants well known to have been found in any given shipment of imported shrimp.

The FDA's failure to prevent the importation of massive amounts of contaminated shrimp has a number of negative effects on the U.S. market, the U.S. shrimp industry and U.S. consumers. First and foremost, farmed-shrimp imports contaminated with banned antibiotics, pesticides and other dangerous contaminants put the health of U.S. consumers at serious risk. Bans on these contaminants are not frivolous -- they are based on sound medical science recognized and applied worldwide.[3] Second, U.S. consumers are quite often unable to distinguish between safe and unsafe shrimp in retail markets and restaurants. Their fear of buying or being served contaminated imported shrimp is real, and it depresses the overall consumption and demand for all shrimp including healthy wild-caught shrimp produced in the United States. Still further, wholesale shrimp buyers know that the large volume of shrimp sourced from farms in countries with lax controls are likely to be contaminated and so they are able to offer lower prices for this shrimp. This practice tends to depress the overall price of shrimp in the U.S. market including that paid to U.S. shrimpers at the dock. Finally, any of the large volume of contaminated shrimp that the FDA's lax inspection system allows into the U.S. market represents shrimp that should never have been part of the U.S. market supply in the first place. This additional supply further distorts (lowers) the price structure for all shrimp in the U.S. market.

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2 See "Shrimp's Success Hurts Asian Environment, Group Says," NATIONAL GEOGRAPHIC NEWS (Dec. 20, 2004) (discussing the Environmental Justice Foundation's "concerns over the levels of antibiotics, disinfectants, fertilizers, pesticides, and other chemicals used by shrimp farmers to maximize profits and combat disease."); Global and Local: Food Safety Around the World, Center for Science in the Public Interest, pp. 14-16 (June 2005); "Chicken from China?," BOSTON.COM (May 9, 2007) ("In China, some farmers try to maximize the output from their small plots by flooding produce with unapproved pesticides, pumping livestock with antibiotics banned in the United States, and using human feces as fertilizer to boost soil productivity. But the questionable practices don't end there: Chicken pens are frequently suspended over ponds where seafood is raised, recycling chicken waste as a food source for seafood, according to a leading food safety expert who served as a federal adviser to the Food and Drug Administration.") (emphasis added).

3 For example, the FDA issued the following findings on the banned antibiotic chloramphenicol, a common contaminant in shrimp imports: "There are at least three known potential human health risks from exposure to chloramphenicol at low dietary levels: (1) aplastic anemia, (2) carcinogenicity, and (3) reproductive toxicity. Concern for these three health risks currently exists at all levels of exposure." Letter from the U.S. Food and Drug Administration to Olsson, Frank, and Weeda, P.C., Re: 02P-0321, p. 17 (Jul. 29, 2003) (emphasis added).

Additional information on health risks caused by banned contaminants in shrimp imports can be found in the SSA's comments to the President's Interagency Working Group on Import Safety at http://www.shrimpalliance.com/Press%20Releases/Comments%20to%20Interagency%20Working%20Group.pdf.

The combination of stringent imported food safety regimes in other major importing markets and lax enforcement of U.S. law encourages the diversion of contaminated seafood to the United States. Canada, Japan, and the European Union ("EU") all do significantly more to protect consumers than the FDA does to safeguard the American public. As a result of more strict enforcement of food safety laws in other seafood importing countries, our nation has become a dumping ground for rejected and inferior seafood products that could not be exported to other countries.

A careful comparison of the food safety regimes of our trading partners with that operated by the FDA makes clear the deficiencies of our system. Unlike the FDA's model, which relies solely on point-of-entry inspection of 1 percent of imported seafood products, the EU, Japan, and Canada all have rigorous systems to ensure the safety of seafood imports throughout the product's life-cycle.[4]

European Union: A central tenet of the EU's imported food safety regime is that a system like that employed by the FDA is inherently flawed and cannot effectively protect the consumer. In describing its import conditions for seafood products, the EU declares that "Spot checks on the end product alone would not provide the same level of safety, quality and transparency to the consumer." The EU guarantees equivalence in food safety controls by conducting foreign on-site inspections and certifying exporting countries and individual exporters prior to importation of a product. In addition, the EU currently inspects 20 percent of seafood imports at its borders.

Japan: Japan has a strict risk-based system that is reinforced by high inspection rates, certification requirements and significant penalties for noncompliance. Annually, Japan assesses the risks posed by different types of imported food products, and issues inspection guidelines for the upcoming year based on risk potential. Thus, while the general inspection rate of imported foods is 10.2 percent, the food safety risks posed by imported shrimp have resulted in annual inspection rates of around 25 percent. In addition, Japan's food safety agency has the authority to issue mandatory 100 percent testing and absolute import bans of a particular product and/or a particular country if it finds that more than 5 percent of consecutive shipments of the inspected import is adulterated. For example, Japan instituted compulsory testing of 100 percent of Vietnamese shrimp imports in December 2006 after repeated detection of chloramphenicol, a banned antibiotic, in shipments of Vietnamese shrimp.

Canada: Canada imposes a minimum standard inspection rate of 15 percent for all imported seafood products and has strict importer licensing requirements. Exporting countries with bilateral equivalence agreements with Canada are

[4] For a comprehensive description of the imported food safety regimes of the EU, Japan, Canada, and the FDA, please refer to the SSA's comments to the President's Interagency Working Group on Import Safety at http://www.shrimpalliance.com/Press%20Releases/Comments%20to%20Interagency%20Working%20Group.pdf.

> subject to reduced inspection requirements. In return, the exporting country agrees to inspect and certify products bound for Canada. In Canada, if an import fails inspection, subsequent shipments are inspected until four consecutive shipments pass inspection. Repeated failure of inspections may lead to the imposition of an import alert and 100 percent testing of shipments from the exporter or exporting country.

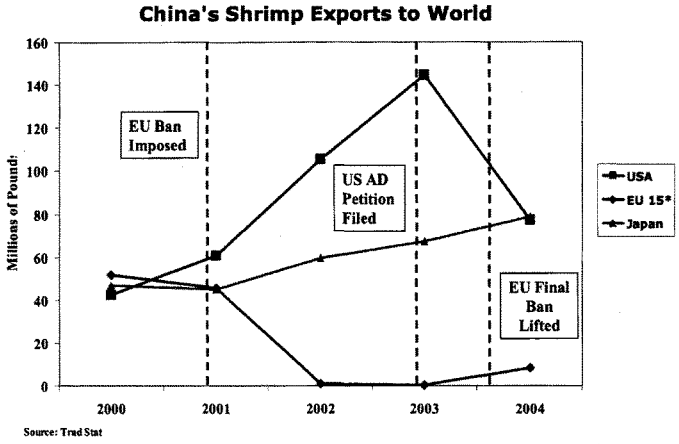
In stark contrast, the FDA does not require certification of equivalence, choosing instead to rely solely on 1 percent inspection of imports. While FDA inspects only about 1 percent of imported food products, an even smaller percentage, 0.2 percent, is tested in a laboratory. Private testing laboratories need not be licensed or accredited by the FDA in order to certify the food safety of seafood imports. Further, the FDA does not quarantine imports at U.S. borders, meaning that importers may take delivery of even the most suspicious seafood imports. On the off chance that an import shipment is rejected, the FDA does not impose any marking requirements nor does it otherwise have any procedures to prevent importers from sending rejected shipments to other U.S. ports (i.e., "port-shopping").

In the absence of effective FDA enforcement, there is nothing to stop shippers, like the company advertising in SeaFood Business below, from importing rejected products through other ports -- either in this country or elsewhere -- with no disclosure of the harmful nature of the product.

Source: SeaFood Business Magazine, p. 52 (Sept. 2007)

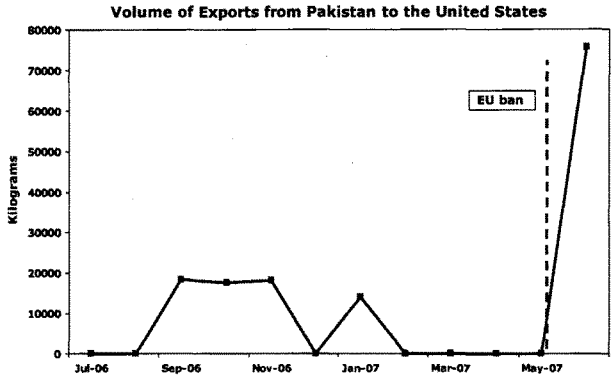
When faced with lax enforcement in the United States and rigorous policing in other markets, it is easy to see why contaminated imports are diverted to our market. Our poor food safety regime has effectively made the United States a magnet for potentially dangerous seafood exports.

The shrimp industry is painfully familiar with the perverse incentives that the FDA's food safety regime has created in this market. For example, when the EU imposed a complete ban on shrimp from China in 2002 because of illegal antibiotic use, Chinese shrimp imports to the United States shot up 30 percent in one year; adding millions of additional pounds of shrimp to this market. The influx of Chinese shrimp imports began to abate only when the U.S. domestic shrimp industry filed an antidumping petition to seek relief from unfairly traded imports.



The same thing happened when the EU decertified Pakistani seafood producers. In early 2007, the EU completed an on-site review of seafood safety systems in Pakistan that revealed numerous and egregious violations of EU food safety standards. Based on these findings, the EU decertified all seafood producers from Pakistan in April 2007. As a result, shrimp exports from Pakistan to the EU plummeted, resulting in no reported exports of shrimp to the EU in June 2007.

At the same time, Pakistan's shrimp exports to the United States skyrocketed in June 2007. In just two months, Pakistani shrimp to the U.S. jumped from zero to 75,000 kilograms, or 165,000 pounds. To put it in perspective, the volume of shrimp exports to the United States from Pakistan in June 2007 was larger -- approximately four times greater -- than the monthly volume of Pakistani shrimp exports to the United States in any previous month since 2005. Again, while the EU has refused to accept shrimp products from Pakistan because of the dangers posed by these products to consumers in the EU, substantial quantities have begun to enter the United States.



Source: Trad Stat

Now we are facing the same problem with Vietnam. Markets in Canada, Japan, the EU, and the United States account for roughly 90% of Vietnam's average annual 268 million pounds of shrimp exports. With the exception of the United States, every major seafood importing market has acted to address the food safety problems posed by Vietnamese seafood products.

Canada: From 2003 to 2005, Canada imposed a country-wide alert and instituted 100 percent testing of all seafood exports from Vietnam after finding repeated seafood products tainted with chloramphenicol. In July 2006, Vietnam committed to inspect and certify that all seafood exports to Canada were free of antibiotics in a bilateral agreement reached to address the problems with Vietnamese seafood exports.

Japan: Beginning in December 2006, Japan began testing 100 percent of all Vietnamese shrimp exports because of repeated chloramphenicol findings. Vietnam agreed to certify 100 percent of their shrimp exports to Japan. Even with the certification system, Japan continues to find antibiotics in Vietnamese shrimp exports. Japan has threatened a complete ban on Vietnamese shrimp products.

EU: In 2007, the EU conducted an on-site inspection of Vietnamese seafood processors and found that while shrimp tainted by antibiotics were not exported to the EU, the contaminated shrimp were not destroyed, leaving open the possibility

that it was exported to other markets with less stringent regulations (like the United States).[5]

While other major importing countries are in near consensus about tainted Vietnamese seafood, the United States, which receives approximately one-third of Vietnam's shrimp exports, has not subjected Vietnamese seafood imports to increased testing. A review of the FDA's import refusals list indicates that the FDA has not refused a single shipment of Vietnamese shrimp based on antibiotics since March 2006.

The FDA has sufficient evidence of the hazards of farm-raised seafood from Vietnam through its own investigations and, as we have been told by reliable U.S. government sources, through direct admissions by Vietnamese authorities of the widespread use of banned substances in the production of farm-raised seafood. And for some of those substances, the FDA apparently has no testing protocols to detect them.

Concerns about the FDA's inability to assure the safety of imported seafood have risen to the point that states have been doing their own testing of seafood imports. And these states have repeatedly found harmful, banned substances in the imported seafood they test -- seafood allowed by the FDA to enter this country. Some notable examples of states taking action against contaminated seafood imports include:

Louisiana: Louisiana has had an Emergency Rule in place since 2002 to test imported shrimp and crawfish for the contaminant chloramphenicol. In 2007, Louisiana required testing for fluoroquinolones in seafood from China and Vietnam.

Mississippi: Mississippi currently tests imported seafood for the presence of fluroquinolones and chloramphenicol, both banned contaminants in food products. Mississippi's laboratories have repeatedly found Ciprofloxacin, Enrofloxacin, and chloramphenicol -- all banned antibiotics -- in imported seafood.

Florida: Florida began testing imported seafood in 2002, focusing its testing efforts on fluroquinolones and chloramphenicol. In 2005, 15 of 19 seafood samples tested for fluoroquinolones came back positive. In 2007, 3 of 16 samples tested positive for fluoroquinolones.

Georgia: Since 2003, the results of Georgia's laboratory tests on imported seafood have repeatedly shown the presence of Ciprofloxacin and Enrofloxacin in imported seafood.

Arkansas: When Arkansas began its imported seafood testing program with the FDA in 2007, the FDA found that one out of the six shipments of imported

[5] In addition, Russia imposed strict certification requirements on Vietnamese shrimp imports in 2007 after finding repeated food safety violations. Singapore has banned several Vietnamese shrimp producers for similar food safety violations.

seafood from China it sampled contained harmful contaminants. Arkansas sought to undertake additional tests, but the FDA expressed an unwillingness to assist with future imported seafood testing efforts. As a result of the FDA's unresponsiveness, Arkansas's Public Health Laboratory devoted significant resources to testing equipment so that it could independently test imported seafood for harmful contaminants.

While we are pleased that state governments have attempted to step into the breach, the burden of ensuring that imported seafood is safe to consume should not be forced upon them. There is no substitute for a strong federal food safety system. Unfortunately, the FDA appears to take action only when facing a crisis or public outrage. We respectfully suggest that this Committee should be outraged.

We believe that the FDA must be made to take responsibility for the safety of seafood imports coming into this nation. As such, we have created an 11-point proposal for legislative reform that would bring the FDA in line with our international counterparts and significantly improve the safety of imported seafood in the United States.

1. Require Equivalence Agreements

   - An exporting country may not export to the United States unless it establishes and certifies that its food safety laws and procedures are equivalent to U.S. standards.
   - Individual exporters within approved countries must certify equivalence with the United States' standards on critical control points in the manufacturing process, monitoring and sampling requirements, and recordkeeping obligations.
   - The FDA would conduct periodic on-site inspections -- at least annually -- of foreign production facilities.

2. Mandate Inspection and Testing Rates

   - At a minimum, the United States should mandate a 20 percent inspection and testing rate for all seafood imports.
   - New exporters to the United States should be subject to 100 percent testing for the first fifteen (15) shipments into the United States.
   - If an importer fails an inspection or test, all subsequent imports are subject to 100 percent testing until fifteen (15) consecutive shipments pass inspection.
   - Repeated failure may lead to the imposition of producer and country bans.

3. Fund FDA Oversight of Private and Public Laboratory Facilities

   - FDA should bolster its own inspection and testing capabilities with sufficient funding for qualified staff and testing equipment.

- Importers would be required to pay an import inspection fee to help offset the cost of inspection and testing.
- Testing should be conducted primarily by the FDA. If test results are issued by private laboratories, then these laboratories must be fully accredited, certified and licensed by the FDA. Such accreditations and licenses must be renewed annually.
- All FDA and private laboratories must test each class of imports based on a standardized list of controlled substances.

4. Limit Imports to Designated Ports of Entry

- Imported seafood are allowed entry only through designated ports of entry staffed with trained inspectors and equipped with proper technical resources for testing and evaluating imported merchandise.

5. Require an Annual Report and Prospective Enforcement Plan

- The FDA should publish an annual report describing significant incidents of import noncompliance and other areas of concern, as well as summary statistics. The report would describe the FDA's plans for addressing these issues in the coming year.
- The FDA would be mandated to implement its enforcement plan within 3 months of publication of the annual report.

6. Authorize Seizure and Destruction of Contaminated Imports

- If an import is found to violate U.S. food safety standards (i.e., contains banned substances), the FDA must seize and destroy the import unless the importer can meet the requirements for re-export.
- The FDA must establish an expedited system of notification between the FDA and port-of-entry officials that a shipment has been rejected and must be destroyed.

7. Limit Re-export of Rejected Shipments

- Rejected shipments will only be released to importers under controlled circumstances within 45 days of notification. Otherwise, the shipment will be destroyed.
- If the rejected shipment is bound for a third country, the importer must first notify that country's food safety agency. The third-country destination must notify the FDA of its acceptance before the rejected shipment is released.
- Rejected shipments must be conspicuously marked "United States Refused Entry."

8. Increase Penalties for Purposeful Deception

   - Knowingly mislabeling, and other knowing violations of U.S. food safety laws, such as "port shopping," will result in significant civil and possible criminal penalties. An importer must certify the product's country-of-origin and the producer and exporter's identities.
   - Knowingly falsifying these certifications would result in mandatory monetary penalties and denial of trading privileges.

9. Authorize Country Bans Until Demonstrated Improvement

   - Systemic detection of prohibited substances would result in a complete ban of a particular product, or all products, from the exporting country.
   - The country ban would only be lifted when the foreign government proves to the satisfaction of the U.S. government that they have met U.S. food safety standards.

10. Authorize Producer Ban Until Demonstrated Improvement

   - Systemic detection of prohibited substances may result in a complete ban of a particular product from the exporter.
   - The particular product is denied entry to the U.S. market altogether rather than issued an import alert that subjects the exporter to 100 percent consignment testing.

11. Mandate International Coordination for Cooperative Agreement and Information Exchange

   - The FDA would monitor and recognize foreign findings and bans issued by certain countries and regional organizations, including the European Union, Japan and Canada. Review of other countries' findings and alerts would help prevent the United States from becoming a dumping ground for inferior products.
   - Currently, there is insufficient exchange of information and cooperation between countries on food safety issues. This makes it easy for importers who are unable to meet the stricter standards of the Japanese and European markets to channel low quality and likely unsafe food products to the United States. Discussion between exporting and importing countries provides opportunities for importing countries to raise safety concerns and for exporting countries to address their compliance abilities. The objective should be for the FDA to achieve parity, or "no less stringent" requirements than other large importing countries.

For the health of our consumers, for the integrity of our nation's food supply, and on behalf of U.S. producers of healthy wild American shrimp, I urge the Committee to seriously consider our 11-point proposal and enact meaningful FDA reform. The FDA

has promised before that it can change on its own, but the evidence demonstrates just how dangerous the FDA's broken promises have become.

Thank you.

Mr.STUPAK. Thank you, Mr. Williams.
Mr. Marler, opening statement, please, sir.

STATEMENT OF WILLIAM D. MARLER, ESQUIRE, MARLER CLARK LLP PS

Mr.MARLER. Thank you.

Chairman and members of the committee, my name is Bill Marler. I am a trial lawyer. My law firm Marler Clark located in Seattle, Washington specialized in representing victims of food borne illness. Unfortunately for my clients and many of the corporations that are going to come after me, I have been in business too long. I thank you for the honor of being allowed to testify before this committee. I am proud of the work this committee has done to try to improve food safety throughout the United States.

Although I have never had the honor to testify before Congress, I have had the honor to be here before in 1994 for Senate hearings about the lack of safety in our food supply. At that time I was with Brianne Kiner, then 9 years old, who spent 6 months hospitalized, suffered acute kidney failure and multiple strokes, had her large intestine removed, was in a coma for over a month, and spent 100 days on dialysis, all from eating a hamburger. Thirteen years later I was here again in April of this year. This time with Ashley and Isabella Armstrong, who I think the committee would all agree were the cutest kids you have ever seen before any committee. Victims of the more recent spinach outbreak that sickened 205, killing five. I was with Sean Pruden, the victim of the E. coli outbreak at Taco Bell, that sickened over 100, and with Terry Marshall, whose mother-in-law has remained in a nursing home to this day after eating a few spoonfuls of salmonella tainted peanut butter. Since 1993 I have had the privilege to represent thousands of Americans, some your constituents. In 2002, during the middle of yet another E. coli outbreak, during the middle of another visit to an ICU to watch a new client struggle for life, attached to more tubes than you can imagine, I penned—for the Denver Post. Here's part of it.

This summer scores of Americans, most of them small children and senior citizens, have already or will become deathly ill after eating ground beef boldly labeled USDA approved. The now infamous outbreak started with a few sick kids in Colorado and quickly spread coast to coast, eventually triggering the recall of 19 million pounds of ground beef tainted with E. coli 0157H7. Because their parents trusted our government's food inspections several kids suffered kidney failure and dialysis, or weeks hooked up to all sorts of machines. For some the long-term prognosis is grim with the risk of further kidney failure, dialysis, transplants or worse. Most of these kids' parents' have hired me to help them get compensation for hundreds of thousands of dollars in medical costs, and the risk of future kidney failure. That may prompt some readers to consider me a blood sucking ambulance chaser who exploits other people's personal tragedies. If that is the case, here is my plea. Put me out of business. For this trial lawyer, E. coli has been a far too successful practice and a heartbreaking one. I am tired of visiting with horribly sick kids who did not have to be sick in the first place. I am outraged with the food industry that allows E. coli and other poisons to reach consumers and a President, Congress and

federal regulatory system that does nothing about it. Stop making kids sick and I will happily move on. That, ladies and gentlemen, was in 2002. The time has finally come to put me out of business. The CDC estimates that there are still 76 million Americans getting sick every year, each and every year, from eating food. That means one in four Americans will contract a food borne illness every year. Hundreds of thousands will be hospitalized and thousands will die. That is the human suffering part. There is also a business part. Billions of dollars will be spent on medical treatment and many more billions will be in lost wages, in recall costs, in the sale of food and yes, in legal fees to defend and prosecute these companies. Civil litigation in America is a blunt instrument for change. It is better for the government and business to work together to eliminate the need for lawsuits and lawyers. When American business poisons its customers and when our regulatory agencies do not have the manpower, willingness, or ability to help businesses perform, people die and market share is lost nationally and internationally. It is time to help business and consumers to simply make me unnecessary. If you fix the food safety system trial lawyers like me will become a small irrelevant footnote in history, but you will be remembered and honored for helping to fix a broken system.

The issue of food safety is not new, of course. A century ago Upton Sinclair's book The Jungle exposed both contamination of meat processing and corruption that led inspectors to look the other way. What has changed since Upton Sinclair's time? Are we better off than we were 100 years ago? A year ago I was asked by the spinach and lettuce growers of California to address them in Salinas. Considering that by then the leafy green industry was on its knees financially and I had lawsuits pending in several states, it was a bit of a tense lunch. Why was I invited? I am frankly still not sure, but why I was suing them was all too clear. In the prior 10 years there had been 21 outbreaks related to fresh leafy products with hundreds sickened. In 2006 hundreds became sick and five died from eating E. coli contaminated spinach, followed quickly by lettuce outbreaks at Taco Bell and Taco John. The common denominator, California lettuce and spinach and more lawsuits. Mexico banned the importation of California spinach and lettuce. I told the quiet audience of growers and producers a story that I believe at the time to be true. I told them I had seen, since the 1993 Jack-In-The-Box case, I told them what seemed to have happened after the Jack-In-The-Box crisis was the incidence of E. coli seemed to decline. In fact, the CDC indicated by the year 2006 that E. coli cases tied to ground beef had gone down by 42 percent. I told them that they should immulate what the beef industry did. That the beef industry had worked hard to put me out of business. And the reason I can say that is because during that 2003 to early 2007 I had no ambulances to chase because I simply had no E. coli victims tied to E. coli—not tied to hamburger. And in the spring of 2007 started with an ominous uptick in E. coli recalls and illnesses, and ended with hundreds sickened, 33 million pounds of meat recalled. And guess what? More sick and dead children. And guess what? More lawsuits. China banned the import of U.S. beef. And if you

ask the USDA and industry to explain this uptick, they have none. It is unacceptable.

Although things are certainly different from Upton Sinclair's time there are some big similarities, and certainly some things that are new and different challenges. First, there is a terrorist threat to our food system. Just as too many could not imagine the horror in 9/11, too many cannot envision the kind of food disaster today. When a terrorist attacks our food system it will look eerily similar to any other outbreaks of food borne illness. Second is the growth of imports. Sinclair could not have imagined a world where the meat that may be in one hamburger could originate in Argentina, Canada and Colorado, or that we would have vegetables year round from South America, Asia and Africa. It is with these two enormous issues in mind I offer five suggestions of how to finally put me out of business.

First, create a local, state and national public health system that catches outbreaks before they balloon into personal and business catastrophe. CDC pulsejet and food net, as one of the members mentioned, were launched after the Jack-In-The-Box outbreak and are rightly credited for helping reduce the size of outbreaks by helping more quickly conclude the suspect product was causing harm. But surveillance of human bacterial and viral disease is lacking. For many food borne illnesses, for every culture-positive case 20 to 50 other cases are missed because of lack of surveillance. Most people who become ill with a bacterial viral disease are either seldom seen or never cultured. The more people are tested, the greater the likelihood that a source, accidental or not, will be found sooner.

Second, actually inspect and sample food before it is consumed. At present local and state authorities, along with the USDA and FDA, employ thousands of inspectors across the nation and world to inspect tens of thousands of plants that produce billions of pounds of food. The GEO has warned that our food sampling and inspection system is so scattered and infrequent there is little chance of detecting microscopic E. coli, or other pathogens for that matter.

Third, consider mandatory recall authority on all food products. Recalls must be completed transparent. If a recall is ordered consumers need to know what in fact is being recalled. Full disclosure must be the rule. Under the present system of voluntary recalls, last September we saw the disastrous Tops recall, where the company knowingly left E. coli contaminated product on store shelves weeks after being confronted with an ill customer, and his product both testing positive for E. coli.

Fourth, merge and then adequately fund the three federal agencies responsible for food safety. Right now USDA and FDA share this mission with the CDC. The system is, in a sense, trifurcated, which leads to turf wars and split responsibilities. We need one independent agency that deals with food borne pathogens. You have a moral responsibility to consumers in your home town or anywhere U.S. goods are sold. It is time to adequately fund our health and safety authorities to help businesses protect the consumers.

Finally, we cannot completely regulate ourselves out of this. Standards need to be set with the entire food chain at the table, from farmer to manufacturer to retailer and customer. Standards must also be based upon good science. We must invest in solid research at our land grant institutions to help producers manufacture food that is safe, nutritious, and the envy of the world.

Thank you very much.

[The prepared statement of Mr. Marler follows:]

WRITTEN TESTIMONY BEFORE THE COMMITTEE ON ENERGY AND COMMERCE

Chairman and members of the committee, my name is William Marler. I am a trial lawyer. My law firm Marler Clark, located in Seattle, Washington, specializes in representing victims of foodborne illness. Unfortunately, for my clients, I have been in business too long. It began in 1993 with over 700 people sickened, hundreds hospitalized - many with life-long complications - and four deaths - stemming from the Jack in the Box E. coli outbreak.

I thank you for the honor of being allowed to testify before this committee. I am proud of the work that this committee has done to try to improve food safety throughout the U.S. This will be my first time testifying before the U.S. Congress. Although I have never had the honor to testify, I was there in 1994 for Senate hearings about the lack of safety in our food supply. I was with Brianne Kiner, then a nine year old girl, who spent six months hospitalized, suffered acute kidney failure and multiple strokes, had her large intestine removed, was in a coma for over a month, and spent 100 days on dialysis, all from eating a hamburger. Thirteen years later, I was here again, this time with Ashley and Isabella Armstrong – victims of the more recent Dole Spinach E. coli outbreak that sickened 205, killing 5; with Sean Pruden - a victim of an E. coli outbreak at Taco Bell that sickened nearly 100; and with Terri Marshal, whose mother-in-law has remained in a nursing home since December 2006 after eating a few spoonfuls of Salmonella-tainted peanut butter.

Since 1993, I have had the privilege to represent thousands of Americans - some your constituents. In 2002, during the middle of yet another E. coli outbreak, during the middle of another visit to an ICU to watch a new client struggle for life attached to more tubes than you can imagine, I penned an Op-ed for the Denver Post. Here is part of it:

> This summer, scores of Americans, most of them small children or senior citizens, have already or will become deathly ill after eating ground beef boldly labeled "USDA approved." The now infamous outbreak started with a few sick kids in Colorado and quickly spread coast-to-coast, eventually triggering the recall of 19 million pounds of ground beef tainted with E. coli O157:H7.
>
> Because their parents trusted our government's food inspections, several kids suffered kidney failure and spent days or weeks hooked up to kidney dialysis machines. For some, the long-term prognosis is grim, with the risk of further kidney failure, dialysis, transplants or worse.... Most of those kids' parents have hired me to help them get compensation for hundreds of thousands in medical costs and the risks of future kidney failure. This may prompt some readers to consider me a blood-sucking ambulance chaser that exploits other people's personal tragedies.
>
> If that is the case, here is my plea: Put me out of business. Please.

> For this trial lawyer, E. coli has been a far too successful practice - and a heart-breaking one. I am tired of visiting with horribly sick kids who did not have to be sick in the first place. I am outraged with a food industry that allows E. coli and other poisons to reach consumers, and a President, Congress and federal regulatory system that do nothing about it. Stop making kids sick - and I will happily move on.

That was 2002. Ladies and Gentlemen, the time has finally come to put me out of business. Today, the CDC estimates that there are still 76 million cases of foodborne illness annually. That means one in four Americans will contract a foodborne illness every year. Hundreds of thousands will be hospitalized and thousands will die. That's the human suffering part.

There is also the business part. Billions of dollars will be spent on medical treatment and many more billions will be lost in wages, in recall costs, in the sale of food, and yes, in legal fees to defend and prosecute these companies. Civil litigation in America is a blunt instrument for change. It is better that government and business work together to eliminate the need for lawsuits and for lawyers. When American business poisons its customers, and when our regulatory agencies do not have the manpower, willingness or the ability to help business perform, people die and market share is lost, nationally and internationally. It is time that we help business and consumers to simply make me unnecessary. If you fix the food safety system, trial lawyers like me will become a small, irrelevant footnote in history, but you will be remembered and honored for helping to fix a broken system.

The issue of food safety is not new, of course. A century ago Upton Sinclair's book "The Jungle" exposed both contamination of meat processing and the corruption that lead inspectors to look the other way. What has changed since Upton Sinclair's time? Are we better off than we were 100 years ago?

A year ago, I was asked by the spinach and lettuce growers of California to address them in Salinas. Considering that by then the leafy green industry was on its knees financially and I had lawsuits pending in several states, it was a tense lunch. Why I was invited? I am still not so sure, but why I was suing them was all too clear, in the prior 10 years there had been 21 outbreaks related to fresh leafy products with hundreds sickened. In 2006, 205 people became sick and five died from eating E. coli contaminated spinach, followed quickly by lettuce E. coli cases at Taco Bell and Taco John's. The common denominators – California lettuce and more lawsuits. Mexico banned the importation of California spinach and lettuce.

I told the quiet audience of 250 growers and producers a story that I believed at the time to be true. I told them about what I had seen since the 1993 Jack in the Box case. I told them what seemed to have happened after the Jack in the Box crisis was that incidences of E. coli in meat seemed to decline. First slowly and then more rapidly. I told them how I believed that the problem – through governmental oversight and industry know how. I told them that I had lived to see one of the major food safety success stories of

our time. According to the CDC, E. coli outbreaks linked to tainted meat had declined by 42 percent through 2006. I told them that they should emulate what the beef industry had done to put me out of business, because they had. From 1993 to 2002, nearly all of my work was E. coli cases tied to hamburger. In 2003, one year after the recall of 19 million of pounds of meat, I had no ambulance to chase. I had no one to sue on behalf of victims of tainted hamburger because I had no victims.

And then the spring of 2007 started with an ominous "uptick" in E. coli recalls and illnesses and ended with hundreds sickened, 33 million pounds of meat recalled, and guess what? More sick and dead children, and yes, more lawsuits. China banned the import of some US beef. If you ask the USDA and industry to explain this "uptick," they have none. That is unacceptable.

Things are different from Sinclair's critical view of packing plants of the 1900's. We now face things Sinclair could not even begin to imagine. Those two things must drive food safety decisions now. The first is the threat of terrorist attacks via the food system. Just as too many could not imagine the horror of 9/11, too many cannot envision this kind of food disaster today. When a terrorist attacks our food system it will look eerily similar to any other outbreak of foodborne illness. Second, is the growth of food imports. Sinclair could not have imagined a world where the meat that may be in one hamburger could originate in Argentina, Canada and Colorado or that we would have fruits and vegetables year-round shipped in from South America, Asia and Africa. It is with these two enormous issues in mind, that I offer suggestions on how to put me out of business.

First, create a local, state and national public health system that catches outbreaks before they balloon into a personal and business catastrophe. Everyone believes that the Jack in the Box outbreak started in Seattle in January 1993. It did not. It actually began in November 1992 when young Lauren Rudolph died and another 30 people were sickened in and around southern California. However, because E. coli O157:H7 was not a reportable illness at the time, the death and illnesses were not recognized as an outbreak and the contaminated meat was shipped to Seattle. CDC's PulseNet and Food Net were launched and are rightly credited with helping reduce the size of outbreaks by helping to more quickly conclude what suspect product is causing harm. But surveillance of human bacterial disease is lacking. For many foodborne illnesses, for everyone culture positive case, 20 to 50 other cases are missed because of lack of surveillance. Most people who become ill with a bacterial or viral disease are either seldom seen or never cultured. The more people are tested, the greater the likelihood that a source, accidental or not, will be found sooner.

Second, actually inspect and sample food before it is consumed. At present, Local and State authorities, along with the USDA and FDA, employ thousands of inspectors across the nation and world to inspect tens of thousands of plants that produce billions of pounds of food at farms, processing plants and retail outlets. The GAO has warned in the past that our food sampling and inspection is so scattered and infrequent that there is little chance of detecting microscopic *E. coli* or any other pathogen for that matter.

Third, consider mandatory recall authority on all food products. Recalls must be completely transparent. If a recall is ordered, consumers need to know what in fact is being recalled. Full disclosure must be the rule. Under the present system of voluntary recalls, last September we saw the disastrous Topps recall where the company knowingly left E. coli contaminated product on store shelves three weeks after being confronted with an ill customer and its product both testing positive for E. coli O157:H7. But recalls are not perfect. Although stunned by the video of animal abuse at Hallmark/Westland, I am more stunned that the recall has ballooned to 143 million pounds of meat and is quickly encompassing products that might contain trace amounts of the meat. No people have been sickened. I wonder if resources are better spent elsewhere.

Fourth, on a national level, merge and then adequately fund the three federal agencies responsible for food safety. Right now, USDA's Food Safety and Inspection Service and the inspection arm of the Food and Drug Administration share this mission with the CDC. The system is trifurcated, which leads to turf wars and split responsibilities. We need one independent agency that deals with food-borne pathogens. You have a moral responsibility to consumers in your hometown or anywhere U.S. goods are sold. It is time to adequately fund our health and safety authorities to help business protect their customers.

Fifth, we cannot regulate ourselves out of this. Standards need to be set with the entire food chain at the table – from farmer, to manufacturer, to retailer and customer. Standards must also be based upon good science. We must invest in solid research at our land grant institutions to help producers manufacturer food that is safe, nutritious and the envy of the world.

None of this will stop bacterial and viral illnesses entirely. These invisible poisons have been around a long time. However, these five steps will enable us to help prevent it, help detect it far more quickly, to alert stores and families, and to keep our most vulnerable citizens - kids and seniors - out of harm's way. Thank you Mr. Chairman. I am happy to answer any questions.

Mr.STUPAK. Thank you.

We will begin with questions. Members will have 5 minutes for questions.

Dr. Greger, if I may start with you. In your investigation at the Westland/Hallmark, did you investigator ever observe the company alerting USDA inspections or inspectors of the cattle that went down after the 6:30, and I think you said, 12:30 inspection?

Dr.GREGER. Never. The investigator did not witness it or hear anyone talking about getting the inspector back to look at these animals that had subsequently gone down after antemortem inspection.

Mr.STUPAK. And I take it from the video the person who did the video here was fairly close to what was going on in order to make those—that video.

Dr.GREGER. The investigator is what was called a pen worker, essentially doing exactly that. Unloading these animals, getting them through the pens, and finally into the kill chute.

Mr.STUPAK. OK. Let me ask this, because it came up in the opening statements. If your investigator was at the plant in, I believe you said the Fall of 2007, why didn't the Humane Society notify USDA, the School Lunch Program, about what was happening at the plant before the end of January?

Dr.GREGER. This investigation took over 2 months to complete. It was shot—he worked at the plant in October, November. We gave this evidence over to the local district attorney's office the San Bernardino County district attorney, and they asked us not to publicly release this information. To hold off so they could carry out their own criminal investigation into the animal cruelty that was witnessed. We complied with that request, but by January, after a month had occurred, we felt we had to go ahead, and so we indeed contacted USDA and then made it public. But the fact that downers were being slaughtered for human consumption, this is something that is allowed under the 2007 USDA loophole, and something that the USDA's own inspector general found was happening across the country.

Mr.STUPAK. I was going to ask you to explain that a little bit more, the rule of antemortem inspections of downer cattle. As long as the—when the inspector looks at it and/or sees the animal, and if the animal is standing it can be used for slaughter. If the inspector leaves, it falls over, it can still be used for slaughter?

Dr.GREGER. Let me——

Mr.STUPAK. Or human consumption?

Dr.GREGER. Let me kind of explain the chronology of this loophole. In 2000 USDA declared that they would not be using beef from downed animals. Evidently agreeing that this meat was too risky to be fed to kids at school, but evidently not too risky to feed the kids once they get home from school, or to adults for that matter. We have for years been pushing for a complete downer ban, but it took a case of mad cow disease in the United States, December 23, 2003, before finally, then Secretary Veneman, within a week, said we will have no downer animals, downer cattle being allowed into the American food supply, no exceptions. And a week after that they published their interim final rule in the federal register, January 12, 2004, again no downers, no exceptions. And then

even after, in 2006, when the Inspector General published their critique saying that downed animals were, indeed, going to the food supply. In July 2007 when this rule was finalized, instead of strengthening the rule, realizing that there wasn't proper enforcement, they critically weakened the rule codifying in a loophole, which allowed for animals that went down after antemortem inspection to on a case by case basis with the inspector's approval be allowed into the American food supply. So, you know, live cows can be fed to people, dead cows can only go to pet food or animal feed: pigs, pets and poultry. But you get more per pound if the animal can, indeed, enter the National School Lunch Program, then can be just going to canned pet food. And so if downed animals were indeed lumped in as they should be with dead animals and only fed to pets, for example, then if a downed animal arrives on a truck, just like when a dead animal arrives on a truck they would be thrown—they would be euthanized and thrown on the dead pile. There's no incentive for the workers to kind of prolong their misery. But if some downed animals may—if there is a loophole that is saying some downed animals may indeed be passed for inspection into the food supply, then you see the financial incentive for the workers to, basically by any means necessary, force these animals up to walk back and forth in front of the inspector. And that knowing full well if the animal goes down after inspection then the inspector can pass that downed animal into the food supply. Even if the animal is down and completely non-ambulatory, and even if it appears that this cow was just down because they broke a leg, an animal shouldn't just break a leg at slaughter plant. Either this animal is mishandled or maybe the animal was sick, you know, confused, unsteady gait, and that is why they fell down. That is why Linda Detwiler, the head of the BSE Surveillance, the previous head of the USDA BSE Surveillance Program, has explicitly written to the USDA saying that injury and illness are interrelated. If a cow is down, if a cow cannot walk to the kill box it should not be slaughtered for human consumption. OK.

Mr.STUPAK. My time is up and I still had questions for Mr. Williams and Mr. Marler, but we are going to move right on. We will go for a second round, and I am going to try to keep members to five minutes, because I know you are bouncing back and forth between the different hearings.

Mr. Shimkus, for questions.

Mr.SHIMKUS. Thank you, Mr. Chairman. This is, again, a very important day and very frustrating, very sad. So some interesting points have been raised and what we want to follow up on is—Mr. Marler, first of all, I appreciate that work you have done, and your testimony is pretty interesting because—and I have dealt with the trial bar quite a bit. And, you know, I have a lot of friends. I am from southwestern Illinois, Madison County, St. Clair County. Friends, but not always allies in the debate. I mean they always remind me of, you know, what the vast majority are trying to do is, you know, is take up the cause for those who can't fight for themselves. And I think your record has been one of doing that. But you also, in your testimony, you also make some interesting statements about how instead of the punitive adversarial relationship, that if we really want to get to a place where, I think, we all

want to be regardless of what side of the dais we sit on. That is a credible food safety environment where when, you know, it is easier for our female members to talk about going to the grocery store, talk about feeding their children. Men are less compassionate, you know, neanderthal sometimes.

Ms.DEGETTE. Excuse me. But you don't go to the grocery store?

Mr.SHIMKUS. I do. I'm a Jif guy though, OK, and a Banquet Pot Pie guy, so I am limited in my purchases. The—but talk about this relationship about government regulation and corporate responsibility and how in working together. One of your comments talks about how—the two things I want to focus upon is that, and also the scientific research dollars that you identify is kind of outside this whole purview. Because it talks about the formation of pathogens, how they migrate and how, you know, that is something that we may or may not be doing that good of a job then. Can you address those two?

Mr.MARLER. You know, in 15 years of taking the depositions of, you know, many corporate leaders and workers very few of them have I ever come away with a sense that they did it on purpose. Mistakes happen, failure in their system happen. These bugs are different. You know, in 1982 0157H7 didn't even exist as a known pathogen. Many of the rules and regulations that USDA goes by, you know, go back into the '50s and '40s and '30s. They haven't caught up to somehow some of these pathogens change. I think putting more money in research dollars in our land grant institutions to figure out—and you'll hear this from the corporations that follow me. Some of the outbreaks, they don't even know how they happen. And, you know, to be honest with you I don't even know how they happened. And a lot of times in the litigation we explore the edges or sort of the dirty edges of that. But the reality is that U.S. corporations, it is bad for business to poison consumers. And to the extent where, I think, government can be most helpful is not to try to look for punitive action against corporations, but is really to be sort of a—to work with them both in the research area. And then to set aside good science based regulations that help these corporations do the thing that they really want to do, which is ultimately the right thing.

And I, you know, granted if you did those things you wouldn't have a kind of trial bar, because we would have to go with something else.

Mr.SHIMKUS. Thank you. And Dr. Greger, I want to follow up with my remaining time and appreciate what you have done. That is very frustrating. From southern Illinois, a rural area, beef, pork producing area, corn, soy beans, livestock of all sorts, it is, I mean it is the same business types. And you look at the time, effort and energy that is going on with these individuals who try to move these downer cows, and you think about real time processing you think they are losing time. I mean the time and effort to move these instead of just segregating them, getting them through the process.

So I want to follow up on just one of the reports that you cite, which is the audit report from January 2006. Dr. Greger, you claim that the slaughter of downed cattle is a widespread problem. That 29 were put to slaughter, however, in this report that you rely for

this information, and it indicates that only 2 of the 12 plants inspected allowed downer cattle to be slaughtered. To me that would, you know—here is a little chart right here. We want to go after bad actors. I mean we really want to make sure that people who are abusing the system, the available laws, the rules and regulations for whatever reasons, that they are held accountable to the fullest extent of the law. Especially in the report—the film, you keep highlighting California law, you know, this is going on. The law is being broken. And this report highlights two processors, but then it also highlights the other 12—10 that are in compliance. So I guess our question will be focus in on the bad actors and making sure that those who we think are good actors remain good. But is it a systematic world problem of this country, or is it a problem of a few bad actors that we need to be concerned about?

Dr.GREGER. It is a problem with these dairy cow slaughter plants. And that is what the IG report found, and that is what we found at this plant. This was essentially, what we found out later, a magnet plant for what are called "spent" dairy cows. Dairy cows under current production only last about 4 years before being kind of ground to hamburger. So this plant brought downer cows from states surrounding California to this plant. In fact, between 90 and 95 percent of the cows at this plant were dairy cattle, not beef cattle. And it is these—and USDA estimates, perhaps, 295,000 downed cattle every year. It is probably more, maybe half a million is the latest estimate. But these are predominately dairy cattle at the end of production who are spent, who may have metabolic problems, who may have mastitis, infections of the utters, who may be lame for other reasons who are transported long distances to get to these plants. If we had a complete downer ban, if these cows—if it wasn't worth transporting these animals, then presumably they would be euthanized on the farm. And even better there would be an incentive for producers to prevent these animals going down in the first place by providing adequate bedding. Up to 90 percent—for example, according to Dr. Grandin, a livestock consultant, up to 90 percent of downers are preventable. And so if you can't get money from a downer cow then there won't be this incentive to continue to send them and process them.

Mr.SHIMKUS. OK. Thank you, Mr. Chairman.

Mr.STUPAK. Mr. Doyle, for questions, please.

Mr.DOYLE. Thank you, Mr. Chairman. I just have a couple questions.

I am really intrigued by this financial incentive. It makes a lot of sense to me to ban downer cows. I am trying to understand. When you saw that video and these workers spending all that time and effort to get these cows to stand up—I don't know much about the slaughter business. What is that—I mean is there a financial incentive to those workers? Are they somehow paid on how many—to go through that extra effort to shock and forklift and roll and do all that stuff we saw on the film. And where does that financial incentive sit? At the supervisor's level? I mean do these workers have some financial interest in getting those cows to stand up?

Dr.GREGER. Well, finally the criminal testimony has been published from the San Bernardino district attorney's office. The Chino police did the investigation, and we actually have the kind of writ-

ten transcript. And these workers claim that this was a company policy. That they were under pressure from supervisors to get these cows into the slaughter plant. Again, if they are irreparably down then they may have to just be thrown on the dead pile, and not get those kind of extra pennies per pound that they would be if they were allowed into human consumption. And so they claim that they were just kind of being pressured from above. But if you see more extended—I mean there are hours of videotape. You can see some of the online workers coming out, you know, because the line is stopped because there is a cow actually downed in the kill shoot. And so we have footage where they are shocking animals, actually getting cows to trample over downed cows to get into the kill box. And so when you have an animal that is actually down in these very narrow pens it may actually stop the line completely. And so they are coming out saying, what's the holdup? And so tremendous amount of human resources is used. And the only thing I can imagine is, this industry has kind of a razor thin profit margin and that losing literally hundreds of pounds of beef, even though some of these dairy cattle were quite skinny. I mean potentially losing all that weight and you would hear comments from supervisors saying this cow is too big to be down, because there is weight there that could be sold.

Mr.DOYLE. Well, what is troubling is the pressure seems to be coming from the top. So it is more a culture in that particular corporation at least, which says, you know, we are going to get as many cows into that kill box as we can regardless what condition they are in. It seems rather troubling that that philosophy is going up higher than just at some lower lever. What is the percentage? I am just trying to understand to downer cattle to the total that go into the kill box. What are we talking about in terms of lost, you know, production?

Dr.GREGER. Because of the kind of unique cattle population that was going to this plant, and similar plants like it across the country, our investigator witnessed literally downed cattle every day coming off trucks.

Mr.DOYLE. Ten percent, 20?

Dr.GREGER. He said that typically on a truck there would be at least one downed cattle per truck.

Mr.DOYLE. And how many cows on a truck?

Dr.GREGER. And so 30, 35 animals coming down. And so now this plant slaughtered 500 cows a day. Had the capacity to hold about 1,000, so there was this constant, you know, trying to move these animals through the system, and as you can see, just extraordinary methods used to try to kind of squeeze every last penny out of these decrepit animals.

Mr.DOYLE. Well, it seems to me if you change the financial incentive to keeping cows being able to stand by treating them better. You know, if that is the incentive that seems a much better way to save money to increase production and certainly is a much more humane way to deal with the situation. And maybe that is one of the things we should be looking at. How do we create an incentive to do it the right way instead of to do it the wrong way?

Mr. Marler, I just have less than a minute. I just have two questions. You said in your testimony between 2003 and 2006 that E.

coli outbreaks linked to tainted meat had declined dramatically. But since last year there has been this uptick in E. coli illnesses and recalls again. Why do you think this is the case and what can companies or the government do to reverse the trend? I mean why do we get—it looked like we got it right for three years and all of the sudden it seems we are headed in the wrong direction?

Mr.MARLER. I think probably unfortunately, my answer might require a full committee hearing on that. And I think there really is a need for a committee hearing on that particular issue. I think if you reach out to the industry and to USDA they won't really have a great answer, but I think I can give you at least—I have reached out to industry. I have reached out to academics, and I think there are a couple of things that are going on. One is that back in 2006 INS rated a lot of slaughter plants throughout the United States, and a lot of really highly qualified, but illegal workers, were forced out of their jobs. And a lot of unqualified, but legal workers, got into their jobs. So that was happening in late 2006. At the same time with the increased gas prices, oil prices, there is more ethanol being used in the system. There is a lot of collocation of ethanol plants with feed lots. There are some studies that have come out of Kansas State University that show that cattle fed the by-product of ethanol production, distillers grain, have a higher quantity of E. coli 0157H7 in their guts than normal cows. So I think you have a number of things happening simultaneously. You have less qualified workers, more E. coli coming into the system, and then I think there is an aspect of just, you know, frankly that some of these companies I think became complacent. It had gone so well for so long. But I can tell you that I have never had more severely injured children in my office in 2007 than I have had since 2002. So something is really wrong. Somebody needs to get to the heart of it. I am not a scientist, but those are some of the things that I have seen that I think you have to look at.

Mr.DOYLE. Thank you. Thank you, Mr. Chairman. I see my time is up.

Mr.STUPAK. Thank you, Mr. Doyle. Mr. Walden, questions.

Mr.WALDEN. Thank you, Mr. Chairman, and thank you for holding this hearing. I think all of us are concerned about our food safety in America, especially as we see the rise of imports coming in, and so I appreciate the testimony of all the witnesses.

I am troubled, though, as a parent of somebody who is in public school in Oregon in the northwest. I don't know if the beef from this plant made it into the food chain there, but I assume some of it probably did. And I remember when we had the hearings on Ketek here, which is a drug, there was a lot of concern about the fact that the FDA sort of put criminal investigations ahead of patient safety. And I feel a similarity here that, perhaps, the Humane Society didn't do that, perhaps did, but maybe in coordination with San Bernardino. Did you say the sheriff's office don't tell——

Dr.GREGER. The district attorney's office.

Mr.WALDEN. So the district attorney of San Bernardino County told you don't tell USDA there is a food problem here?

Dr.GREGER. They told us to wait on any kind of public release of this information.

Mr.WALDEN. Is that different than notifying USDA?

Dr.GREGER. Frankly, the reason we did not go to USDA first is because USDA has a history of not responding to——

Mr.WALDEN. But I want to get to the point here. So the district attorney didn't tell you not to go to USDA. They just said don't make the video public or—is that right?

Dr.GREGER. They asked us——

Mr.WALDEN. Because I would like to know for the DA, Mr. Chairman, if—well, I guess Mr. Chairman's magically disappeared. But is that what happened?

Dr.GREGER. They asked us to hold onto the information while they completed their investigation and——

Mr.WALDEN. Did they notify USDA?

Dr.GREGER. I am not aware.

Mr.WALDEN. Well, it just strikes me. Here we have got the largest beef recall in American history. I think that is correct, 143 million pounds. Secretary Schafer felt that it was a big enough issue to recall it all, even though most of it now has been consumed. So while kids are eating this meat that may or may not be bad, certainly slaughter conditions were unacceptable, and mostly illegal I think under USDA rules. Nobody—so you didn't tell USDA, the district attorney didn't tell USDA. So even if in the past USDA's been bad about doing recalls on a timely basis, they didn't even know in this case?

Dr.GREGER. Well, in fact this plant's behavior had been brought——

Mr.WALDEN. Right.

Dr.GREGER [continuing]. To USDA multiple times.

Mr.WALDEN. A couple of times. I have read that.

Dr.GREGER. And evidently they—nothing was done.

Mr.WALDEN. But you had evidence something was wrong on tape, right?

Dr.GREGER. Well, evidence from the Pomona Valley Humane Society—and SPCA, they also had evidence, which they provided to the USDA. This was back in 1996, 1997.

Mr.WALDEN. No. But I mean in this case?

Dr.GREGER. Yes.

Mr.WALDEN. You had your Humane Society here or locally had the video——

Dr.GREGER. Yes.

Mr.WALDEN [continuing]. Evidence. But that never got to USDA until after the district attorney—or in January. You waited a couple of months.

Dr.GREGER. Until January, and we contacted the USDA before releasing it.

Mr.WALDEN. Let me ask you this. And I wish—I know our jurisdiction doesn't go out to USDA, so I guess that is why we don't have a witness here. But it seems to me that part of the fault clearly is the faults with the company. I mean at least from—allegedly with the companies who are all not getting sued by trial attorneys for, you know, whatever. But clearly USDA, it seems to me, didn't do their job in the plant. Are they not supposed to have inspectors there throughout this entire process observing? And, Mr. Marler, you have got to be an expert on this, and you have done great work for injured kids and families, and I applaud you for that. But isn't

USDA supposed to have an inspector watching as the cattle are unloaded?

Mr.MARLER. The short answer is yes, but you have also seen in the last—just last week about the lack of inspectors, the numbers of inspectors, I think.

Mr.WALDEN. Right.

Mr.MARLER. There is a shortage and——

Mr.WALDEN. What we get at is, because some of what has occurred and Dr. Greger you may insight it as a good service to the public by exposing this problem. But part of what has occurred in each of these has already violated existing rules and regulations. I think——

Dr.GREGER. Right.

Mr.WALDEN [continuing]. Mr. Marler, you said we can't regulate our way out of this. How do we get it so we can trust our food supply? I mean I am just about——

Mr.MARLER. I think the answer is the economic incentive. You have got to figure out the economic disincentive to shove these cows through the system. And whether that is a complete ban on downer cows, a way of, you know, figuring out some sort of tax credit to get rid of the cows humanely. There are certain things to do. With respect to inspectors one of the things I think that needs to be discussed is whether or not more inspectors are necessary.

Mr.WALDEN. Right.

Mr.MARLER. Whether or not some of the new technologies that are available, both in testing and video cameras and all of that, would be available and useful as we all face, you know, difficulties with tax dollars.

Mr.WALDEN. And one other question just for my own sake. Was the meat—do you feel that the meat that was recalled posed a health risk to those who consumed it? Have you had a chance to look at that?

Mr.MARLER. Let me say that I think that this recall, although the video is shocking——

Mr.WALDEN. Yes.

Mr.MARLER [continuing]. There are no ill people.

Mr.WALDEN. Right.

Mr.MARLER. And the risk of BSE is so exceedingly low in this instance that I sort of feel that we could use these resources that we are spending on this recall and the amount of meat that is being recalled. And now it is being expanded into products that might have some trace element of this meat. I think we could probably spend those resources wisely in other areas.

Mr.WALDEN. All right. My time has expired. I really appreciate your work in these areas. Thank you, Mr. Chairman.

Mr.STUPAK. Thank you. Ms. DeGette for questions.

Ms.DEGETTE. Thank you, Mr. Chairman. You know, part of the reason we have to do these recalls on such a broad level like this one is because we don't really have traceability with our meat supply. Is that correct, Dr. Greger?

Dr.GREGER. We——

Ms.DEGETTE. I mean we can't trace back which lots of meat may have contained the meat from those downed cows that we saw on the video, right?

Dr.GREGER. My colleague, Mr. Marler, is probably best able to answer that question in terms of the traceability and in terms of the kind of proprietary——

Ms.DEGETTE. Yes.

Dr.GREGER [continuing]. Of this data. I mean——

Ms.DEGETTE. But I am correct, right, Mr. Marler?

Mr.MARLER. Correct.

Ms.DEGETTE. And so if you can't trace which exact lots these downed cows were in you have to have these broad recalls. That is another piece of legislation I have got, the Trace Act, that I am doing with Congresswoman DeLauro. Because we feel like when Mr. Shimkus goes to the grocery store because his wife sent him and he buys a package of hamburger he can't tell—and this is part of the problem we have with these recalls. He can't tell if he goes to you because his kid gets sick and you, his lawyer, look at the package that the meat came from we can't trace that back to what lots that came from. So we don't know if those lots contained those downed cows, correct?

Mr.MARLER. For the most part that is true.

Ms.DEGETTE. Now you have done a lot of litigation around food safety, and you know that there are some manufacturers actually do have traceability, correct?

Mr.MARLER. Correct.

Ms.DEGETTE. So we could actually technologically do it with meat, right?

Mr.MARLER. My friends at Dole now have instituted some of the most far reaching traceability on their lettuce.

Ms.DEGETTE. And we have heard from them in some of these——

Mr.MARLER. Right.

Ms.DEGETTE [continuing]. Hearings. They do have great traceability and that would help. That would both help consumers have more confidence, but it would also help industry not have to do these massive recalls. And yet unbelievably, Mr. Marler, every time I bring industry in to talk with me about traceability they oppose it. You don't even have to respond to that. You were talking earlier about economic incentives, and I completely agree with that, which is why I think mandatory recall is also a good idea. Let me talk for a minute about the—one of the things you talked about in your testimony was the Tops beef recall from last year, and how E. coli contaminated products were on the shelves for three weeks. Why do you think it took Tops so long to recall that beef?

Mr.MARLER. Well, it was a combination really of Tops and the USDA working or not working in concert. There was an ill child in Florida that tested positive in her stool for E. coli 0157H7. Meat in her freezer tested positive for E. coli 0157H7. It was a genetic match, but the USDA had a rule at the time. They no longer have that rule. The rule at the time was that if, if the meat came from an opened box of—and this was preformed patties——

Ms.DEGETTE. Right.

Mr.MARLER [continuing]. With plastic covers. If it came from an open box they would not institute a recall.

Ms.DEGETTE. OK.

Mr.MARLER. But what happened was they waited. They waited weeks until more victims piled up, and that is when the recall happened.

Ms.DEGETTE. Yeah. Well, OK. So in the ConAgra peanut butter recall this is what happened. There was a couple of years, I think 2004, there was a whistle blower complaint about the peanut butter contamination at the ConAgra plant in Georgia. And so the FDA investigators went in to check it out, and they asked ConAgra to give them some documentation, and ConAgra said no. Because not only do we not mandatory recall, we don't have apparently mandatory document production unless they have got you to subpoena them or us——

Mr.MARLER. But they have given those documents.

Ms.DEGETTE. Well, yes, they have. Because you know why? We had a congressional hearing then in this subcommittee and low, right before the subcommittee hearing ConAgra changed its policy and they did give over the document. Well, then what happened was they actually had complaints and they had a shutdown in 2006, I believe, of the plant from the contaminated peanut butter. But so all of this time you have the complaint, then you have this kind of gray area where people are going back and forth, then finally you actually get people sickened. Then you finally shut—you had the CDC shut the plant down. That was several years later. My view all along has been that if you had the USDA and the FDA with authority to do mandatory recall with hope you wouldn't have to use that very much. That just the threat of a mandatory recall, economically, would make the producers act much more quickly on a voluntary basis. What is your view on that?

Mr.MARLER. I think mandatory recall is in a sense what everybody believes happens. Everybody in the—if you go out to some of the——

Ms.DEGETTE. Just what I said in my opening statement.

Mr.MARLER. Exactly. Everybody believes it, but it is not really the case. In 15 years of representing victims I can tell you unequivocally that there have only been a handful of cases where companies did not quickly do the recall when confronted with the facts. It is—so most companies, in fact——

Ms.DEGETTE. OK.

Mr.MARLER [continuing]. Ninety-five percent of all companies will act responsibly. Whether or not the government wants to take on that responsibility of mandatory recall is something, I think, frankly the government has to think about pretty hard.

Ms.DEGETTE. Thanks.

Mr.STUPAK. Mr. Burgess, for questions.

Mr.BURGESS. Thank you. Mr. Marler, can we just continue on that thought for a second, because this comes up too with the Consumer Product Safety Commission. Another subcommittee where this statement or the philosophical approach that the voluntary recall is, perhaps, the more nimble or agile way to go about getting an unsafe product off the shelf. Because as you just pointed out the companies are themselves anxious if there is what—I got to believe if I am faced with the possibility of a mandatory recall, are you swearing out of rit, that I will be more frightened of the rit that you swear out than I would be of the USDA or the FDA issuing

a mandatory recall. So if I am a company and I am told that there is going to be—the likelihood of voluntary recall I go to take that very, very seriously, I think, because of the blunt instrument that you wield out there. Is that—in the food safety arena is there any parallel with the consumer product area where they say we can be more nimble and more quick with a voluntary recall, rather than going to mandatory route where now we have got to—someone has got to hire counsel. We have got to go in front of an administrative law judge to get this thing proved up. Where it is going to take weeks to get that done, and where as a voluntary recall can be done within days. Is that a fair statement?

Mr.MARLER. I think there is a place for where government investigators and government regulators and companies can find sort of a happy medium on having the stick of mandatory recall, but the opportunity for a voluntary recall. And in an essence, that is what I think for the most part in the food industry that is what happens. There is sort of a——

Mr.BURGESS. I think so too.

Mr.MARLER. And so I think it is one of those sort of things that, I think, that there are some issues, especially with respect to bioterrorism. I think those are some things that I think we have to have a fallback position. The government can ultimately have that responsibility to pull product off the shelf.

Mr.BURGESS. And I can't help myself. I have got to ask you this question. When you had that lunch with the spinach growers what did they serve you?

Mr.MARLER. We had spinach salad and spinach and chicken. I actually—there were about 50 more photographers here in front of me watching to see whether or not I ate the spinach. And I have to tell you I did and it was delicious.

Mr.BURGESS. All right. Well, good. Again, I couldn't help myself. I just had to know. Now, on this issue that is before us this morning with the issue of the Humane Society brought to the floor is—if this had been E. coli in this meat in October would the justification of waiting until the DA had his ducks in a row, would that be something that you would have seen as a positive response to a crisis this order of magnitude?

Mr.MARLER. Well, I think the fact of the matter is that E. coli 0157 is an—and under the USDA food code. And so any time a product has 0157H7, as long as it is hamburger, there are some quirks in the law that allow E. coli 0157H7 to be on other meat products. And that is another thing the hearing probably should be about. But the fact of the matter is that if, in fact, there was a 0157H7 positive it would have been recalled, and so there wouldn't have been a lag. And so I——

Mr.BURGESS. Well, I guess what I am getting at is the issue of scaling. I mean an E. coli contaminate, people on dialysis, people in the ICU. BSE, nobody gets sick——

Mr.MARLER. Right.

Mr.BURGESS [continuing]. Except for three people and there is an issue of scale there. And I guess what concerns me, Dr. Greger, is, you know, you didn't want to go public with it because the DA wasn't ready. But you don't have to go public to go to the USDA. I mean you could do that confidentially, can you not?

Dr.GREGER. We have had experience with the USDA not following up on animal cruelty charges, even when they have potential public health implications. It wasn't illegal to process downed animals. It is illegal to not tell the inspector about it after antemortem. It is illegal to treat the animals like we saw. These were criminal charges, so we went to the state and local authorities, which did the criminal investigation.

Mr.BURGESS. But at the same time there was a public health issue where, in your opinion, some of these were downer cows that should never have made their way into the stream of commerce for school lunches. And, I guess, what is really bothering me is that gap of time where all these lunches are served in November, December and January, and the product is consumed. If you are concerned about the public health aspect, even though the incidents of BSE is far less than if you truly had an outbreak of something as devastating as E. coli, but still if you are concerned about that why not do something? I mean it seems like the USDA could handle that confidentially where it wouldn't mess up the DA's case down the road.

Dr.GREGER. The USDA has procurement policies that disallow downed animals into the National School Lunch Program. But when we were at this plant we didn't know——

Mr.BURGESS. With all due respect that sounds like a bureaucratic answer. I mean I think what the American public wants to know is how can they in the future feel safe knowing that here the Humane Society had some data that is pretty darn important. Important enough for you to come to this subcommittee this morning and show us an emotional film, and not important enough that we don't stop it going into the stream of commerce. That is what the American people don't understand. I mean I realize there can be bureaucratic reasons, but to be quite frank with you I just say those are not acceptable.

I appreciate it, Mr. Chairman. I know I have gone a little bit over. I will yield back.

Mr.STUPAK. Do you want the gentleman to answer?

Mr.BURGESS. If he has——

Mr.STUPAK. Do you want to answer his last——

Dr.GREGER. We were not aware that this was a supplier to the National School Lunch Program while we were doing the investigation. The USDA does not disallow downer meat, but we know that the National School Lunch Program does. So had we known that, perhaps, we would have been able to get that information. But downed animals continue to this day. It is unfathomable to the American public that we continue to allow any downed animals as USDA inspected meat. And so we are hoping that this investigation will not only shore up food safety across the board, but that we will finally have a downer ban. We knew downed animals were going to the food supply, but that is legal. It is legal for downed animals to go into the food supply thanks to the July 2007 USDA loophole.

Mr.STUPAK. OK. Thank you. We are going to go another round of questions here as members. Mr. Inslee, you have not asked questions yet. I'm sorry. And we will after, Mr. Inslee, we will go the second round.

Mr.INSLEE. Thank you. I want to welcome my constituent neighbor, Bill Marler. And, Bill, I want to thank you for your work. You have done as much, perhaps, as Congress in trying to assure food safety over the last decades, and I want to thank you for it. And that work is just beginning, and we thank you for your efforts.

We are talking about the difference between voluntary standards and regulatory legal enforcement standards. My staff handed me a quote from 1906 from Sinclair Lewis and he says, "it is difficult to get a man to understand something when his salary depends on his not understanding it." And it seems to me that that 1906 observation might apply. You and I have talked about the need for standards regarding vegetables and leafy products, and we have talked about the success we have had in the meat industry. Even though we have got a problem here today there were improvements in part because of your litigation, and in part because some of the things Congress did. Can you talk about what you think we ought to be doing as far as leafy vegetables, non-meat products, to try to learn from the experiences in meat to improve our food safety?

Mr.MARLER. I think the first thing that you have to do is, really in many respects, really partner with consumer groups and industry, and your governmental agencies, as well as academia. There is a lot of research that still needs to be done as to how these pathogens get on these products, and why they are able to be transported for a long period of time and, you know, exactly how they operate. And the thing about these bugs too is that they morphin change over time. So whatever regulatory scheme, whatever standards you set, will always be things that will have to be in somewhat fluid motion. But I think the most important thing is to work with industry, to work with consumers, to build safety nets and to create a culture of food safety. There is a real big lack of both solid research, a lack of funding at research institutions, there is a lack of enforcement simply because you don't have enough FDA inspectors. I mean we talked about the ConAgra plant. That inspector was in there in 2005. Most FDA inspectors very seldom, maybe once a year, once every other year, will get to major manufacturing facilities. Those are the sorts of things that really need to change. But, again, it has to do I think first with good solid working relationships with these partners in this room, but also good research.

Mr.INSLEE. You have suggested consolidation of these agencies into one single purpose agency. And I assume because in regard to USDA you think that there is a conflict between the promotional responsibilities of this agency and the regulatory food safety. I am assuming that. Maybe you can comment on that.

Mr.MARLER. As Tommy Thompson said, certainly before he left, it is just really a matter of not whether, it is a matter of when we have a bioterrorism act against our food supply. A bioterrorism act against our food supply will look absolutely exactly like these things on your charts, but it will be somebody that did it on purpose. And my view is that that really should be where Congress needs to focus its energy and attention. And I think that is why, in my experience, especially in cases where FDA, USDA and the CDC are all in a sense in the same pot, there are so many conflicts between those agencies about information sharing, information

gathering that sometimes they stumble over each other for trying to do the right thing. But they just simply stumble over each other, and it slows the process down of being able to figure out what the cause of an outbreak is sooner, rather than later.

Mr.INSLEE. Let me ask you something that may not be a headline grabber, but grabbed my family a few months ago when I had a family member get, you know, sort of violently ill suddenly, which we thought may have been food related. No long-term lasting damage. I didn't have to give you a call. Just some days of great distress. And I suspect that is going on in thousands of occurrences across the country with no sort of reporting system, because there is no real medical intervention. Is this a problem? And number one, what can we do about that sort of lesser severity issues?

Mr.MERLE. I think that—and that is probably something that this committee and Congress is, you know, acutely aware of. That our public health system has some real challenges. And the fact is that even with our concern about bioterrorism we haven't put the money in on the ground for investigators to do testing of victims of potential food borne illnesses. Because, again, that is where you are going to catch it. You are going to catch it in the ER's. You are going to catch it in doctors' offices. And that is where you are going to catch these outbreaks before they balloon into something that is worse. So I think looking at how our public health system operates or doesn't operate, and giving physicians the tools, specifically with respect to stool cultures for vital and bacterial illnesses, would get us a long way there to stopping some of these outbreaks before they get bigger.

Mr.INSLEE. We hope the wisdom from Bainbridge Island becomes the national policy. Thanks, Bill, for being here.

Mr.MARLER. Thanks.

Mr.STUPAK. Going to a second round of questions here.

Mr. Marley, let me ask you this. It is my understanding, you know, we talked about the other recalls. Jack-In-The-Box, we got Tops, and now we got this Westland/Hallmark hamburger area. When you do hamburger, when they go through these slaughter houses, they trim from different animals that are going down and load up the burger, and it is put in a box, and the box can weigh up to 2,000 pounds. And the way we inspect it, you reach in, you take a little bit out, you inspect it. If it passes that whole 2,000 pounds go, correct?

Mr.MARLER. Yes.

Mr.STUPAK. So how do you then really do an inspection of the quality of the meat or the hamburger that is being produced? And as you said earlier it is the dairy cows that sort of is the basis for our hamburger in this country, right?

Mr.MARLER. Seventeen percent of——

Mr.STUPAK. Seventeen percent.

Mr.MARLER [continuing]. Hamburger in the country is from——

Mr.STUPAK. OK.

Mr.MARLER [continuing]. Dairy cows.

Mr.STUPAK. So how do you really get at it if—how do you get at these microorganisms, E. coli, whatever may be there?

Mr.MARLER. When the inspecting system was created in the United States most of the people didn't understand how bacterial

or viral illnesses sickened people anyway. You were looking for things. You were looking to see if the cow had tumors or if it was tubercular. You were looking for those sorts of things. It is a new day now, and these pathogens are out there. Some of them, you know, morph. We have seen new forms of E. coli. Pathogenic E. coli show up in our food system just in the last few years. We have the technology to do scientifically based testing. In fact, one would argue that many of the retail outlets, the Jack-In-The-Boxes, McDonald's, the big retails outlets forced random testing onto suppliers. Which was what I think one of the reasons why E. coli 0157H7 cases went down so dramatically after 2002, because we were testing. It is not a perfect system, but random scientifically based 0157H7 testing can get us a long way to making our food supply safer.

Mr.INSLEE. But after Jack-In-The-Box we came up with the HACCP Program for hazardous detection. But then, as you said here, here is the meat recall that is just in the last 12 months there have been 91 recalls, 63 of them are meat alone.

Mr.MARLER. Right.

Mr.INSLEE. So has government then said well, we have this HACCP system, therefore, industry is self regulating itself. We won't have to do it.

Mr.MARLER. I think that is why that is the problem. You have got to not only—it is not only a partnership with industry to help set the standards so they are actually workable standards that make sense, but I do think that there has to be ultimately your people on the ground in the plants making sure that the kinds of abuses that we saw at Westland/Hallmark don't occur. The sort of follow-up that didn't occur by FDA officials at the ConAgra plant—to make sure that those, in fact, do occur. It is a resource issue. It is a manpower issue.

Mr.INSLEE. Any reason why we should not label meat products that is treated with carbon monoxide or seafood with carbon monoxide to let the consumer know?

Mr.MARLER. No, I see no reason why.

Mr.INSLEE. Mr. Williams, let me ask you this. In your testimony you are talking about shrimp and you are talking about when Pakistan went from 0 to 165,000 pounds. China dumping it here.

Mr.WILLIAMS. Yes.

Mr.INSLEE. What is the danger here? You are saying the FDA isn't inspecting it. Explain this, especially when we are talking a little bit about pathogens and all that in shrimp and other—and you said Vietnam's next on our list we got to watch for?

Mr.WILLIAMS. Right. Well, when another importing nation, such as European, Japan or the European Union, Canada, increases their inspection rates when they find problems, which they do. They inspect up to 25 percent. We inspect less than one percent. When they increase their inspection rate the imports suddenly stop going to those countries and they——

Mr.INSLEE. So in other countries increase their inspections the imports stop, and they get shifted to the United States. So we become the dumping ground.

Mr.WILLIAMS. Exactly, exactly.

Mr.INSLEE. We have had other hearings where it indicates, let us say, like seafood especially, they will bypass our inspections in San Francisco where we have a very good lab and go, let us say, to Las Vegas and bring it in the back door. Is that a continuing problem?

Mr.WILLIAMS. That is the term they use. They call it port shopping. They will send this product to a port that will be the less likely to inspect their product, and if they do inspect it they don't—they have the option of taking it back out of the country or it will be destroyed. Of course they will take it back out of the country and send it to another port with what may not get inspected. You ought to have a 99 percent chance of getting it in without being inspected.

Mr.INSLEE. What are the fungi and antibiotics that may be found in shrimp and other seafood? We had one report that summed the seafood being treated with carbon monoxide. About 20 percent of it was already rotted before it was ever sent to the United States, but the carbon monoxide, of course, masked the problems with the seafood.

Mr.WILLIAMS. Right.

Mr.INSLEE. So what are the fungi and antibiotics we look for?

Mr.WILLIAMS. In seafood there is malachite green. There is a host of nitrofurans, chloramphenicol, which is—causes several irreversible blood diseases such as aplastic anemia. And what is particularly troubling with some of these diseases is you will not see this for probably 10 years down the road. We don't know what amount causes these diseases. That is why we have a zero tolerance on it, and it is banned worldwide for use in food consumption.

Mr.INSLEE. OK. Thank you. Dr. Greger, my time is up at this—what did your undercover—if you know, what did your undercover investigator tell you USDA inspectors were doing? You said 6:30 and 12:30 was their inspections. What were they doing in between?

Dr.GREGER. There are on-line and off-line inspectors. So by law a plant cannot operate without on-line inspectors looking at the carcasses. However, the plant can continue to work if there aren't these off-line inspectors. They are the ones that are looking at the pens and supposedly doing random checks. Not in this case. Not looking at the unloading of animals. Not looking at them antemortem, before the slaughter of these animals. And so the plant can continue to operate. So in a situation of understaffing the inspectors are in the plant on the line and others, you know, may get out or maybe between multiple plants. I mean in some areas of the country there are more severe understaffing issues than others.

Mr.STUPAK. OK. Thank you. Mr. Shimkus, questions.

Mr.SHIMKUS. Thank you. Let me just follow up Dr. Greger one more time on the whole terminology of downer. These are dairy—spent dairy cattle?

Dr.GREGER. Yes.

Mr.SHIMKUS. Spent dairy. And they are shipped from multi-state regions, so they arrive—downer means they are down, right? That is kind of the definition. They could be down for a lot of different reasons?

Dr.GREGER. Correct.

Mr.SHIMKUS. We—obviously mad cow. People—we know that. But downer doesn't mean that all these are mad cow. They could

be just fatigue and major fatigue. They could have been going without food and water for multi-hours over the road haul. So, and you mentioned one per tractor trailer load. What should have this processor done? Should they have—and think if he was processed. Just segregate the downed cattle? Could they have allowed that downed cattle then time to recover if it was just fatigue and water to then, without assistance, get up on its own and then process through the veterinarian check and then—or by definition once down, always down regardless of the reason it was down?

Dr.GREGER. Well, what should have happened—I mean downer animals are veterinary emergencies and should be treated as such, and they should receive individual veterinary treatment or they should be humanely euthanized. But there is a system in which one can segregate so-called "suspect" animals, and see if indeed they can perk up and are able to walk on their own. And then by definition they are no longer downer cattle. At this plant there was no suspect pen. There were no suspect stickers.

Mr.SHIMKUS. If they would have just moved all these downed cattle to a pen, a suspect pen, and then monitored those and those that were able to revive processed back through, and those who can't then deal with them as per law.

Dr.GREGER. The problem is, is it is very difficult to humanely transport these downed animals. Hundreds of pounds and so how are you going to do it? As you can see——

Mr.SHIMKUS. Right.

Dr.GREGER [continuing]. Forklifts and chains. I mean there are humane ways to do it via these sleds and—but it is something that is, you know, much more intensive and——

Mr.SHIMKUS. Right.

Dr.GREGER [continuing]. It may just make more sense to euthanize them on the spot certainly.

Mr.SHIMKUS. Thank you. The—and, Mr. Williams, thank you for your patience. I am glad the Chairman directed some questions. On this whole imported shrimp, who makes the wholesale purchases of this imported shrimp?

Mr.WILLIAMS. I am sorry?

Mr.SHIMKUS. Who makes the wholesale purchases of the imported shrimp?

Mr.WILLIAMS. That would be mostly the importers and distributors.

Mr.SHIMKUS. And what obligations do the firms who are purchasing through the wholesalers have in testing the shrimp?

Mr.WILLIAMS. I am sorry. Say that again.

Mr.SHIMKUS. Well, here is my frustration in the food processing perspective. It is not a cost benefit to business, especially with the ability of litigation, food recalls, you know, to—I actually have a hard time believing that companies willfully, for a profit margin, allow unsafe foods to the market. I believe, I think, that there are mistakes and errors. There is evolution to these pathogens. We need to do more science to figure out how to stop this stuff. In the manufacturing process if you are building a car and you are going to a—you got a wholesaler who is creating the widget and has to be one millimeter of inch, it is tested before it is exported to the assembly line. And when the person receives it they are testing to

make sure it is within the specifications. So isn't there testing on both? Shouldn't there be testing on both ends?

Mr.WILLIAMS. There is testing on both ends. We are under strict Federal, State and local guidelines, or health guidelines, to test our product whether they are imported or not. But once they reach these shores and the FDA allows them in because of their lack of testing we don't test for chemicals. Our shrimp are not tested for illegal antibiotics or chemical contamination. We are tested on the safety and the quality of it going out to the consumer.

Mr.SHIMKUS. Should we?

Mr.WILLIAMS. I don't know. They shouldn't be allowed in because there are no chemicals in domestic shrimp.

Mr.SHIMKUS. Right.

Mr.WILLIAMS. Those shrimp should be tested before they leave the foreign nations.

Mr.SHIMKUS. Right.

Mr.WILLIAMS. And here also before they come into our market.

Mr.SHIMKUS. And I think there is credible debate on the—we definitely don't want to be the dumping ground when other countries have established some standards, you know. Not always when you set standards—hopefully they are scientifically based. That makes sense. And then we don't want to be the overflow and the dumping ground for that. But I also think it is just not good business if you know that there are additives in foods that affect the people that you are trying to sell your product to. To not test—establish those standards and not purchase it if it doesn't meet those standards.

Mr.WILLIAMS. Well, I agree. And therein lies the problem that, you know, these shrimp should be tested. We should have at least equivalence with the foreign countries as we do here. Have it at least the same amount of testing over there as they do here. In 2006, for example, the FDA tested 2,480 inspections of domestic fish and fishery products here in the United States. Only 200 in the foreign nations, and we imported over a billion pounds of shrimp that year. And we produced 200 million.

Mr.SHIMKUS. And so your basic premise is our domestic standards are much higher than our imported standards.

Mr.WILLIAMS. Well, yeah. We think the—yeah, the health standards are. Yes, but like I said we don't test for chemicals.

Mr.SHIMKUS. Right, OK. Thank you, Mr. Chairman.

Mr.STUPAK. Mr. Walden, questions.

Mr.WALDEN. Thank you, Mr. Chairman. I want to make a point that getting back to this issue of the malachite green, which was the carcinogen in eels. Which, I guess, South Korea banned in July of '05, and then Canada in January of '06. And it took our FDA another 8 months after, or 7 to figure it out. But what do we need to do here?

Mr.WILLIAMS. Well, I think we have put together what we think is a very comprehensive food safety program that the FDA should adopt and put in place. And, you know, I have heard that we can't inspect our way out of this mess. That may be true, but we can certainly do a better job than what we are doing. But I think if they look at our—in our written comments if you will look at our safety

program that we think is very comprehensive and would take us out of this mess.

Mr.WALDEN. OK. I guess as a consumer, you know, and I have supported country of origin labeling and all, and then been shocked as I go down the seafood display at my local grocery store just where stuff comes from. I wanted assurance that what I am buying for my family is safe.

Mr.WILLIAMS. Yeah.

Mr.WALDEN. And I will tell you, Mr. Chairman, every time I come to one of these hearings you are holding I walk away thinking what can I eat, you know, or what vitamins should I take, or what prescription should I avoid. And it is just very troubling, and yet we know overall our food supply is pretty darn safe and secure. But so I think we are trying to find out where the hole is. Where are the breaches? What do we need to fix here? When you think of how much food is produced and consumed without any problem. I mean these are kind of along the edges, but it is not along the edge when it is your son or daughter that is hooked up to feeding tubes or dies. And that is—we want to get to zero tolerance. And it sounds like most importantly we need a better inspection regime and more inspectors. It sounds like, at least with FDA and probably USDA, we need more real time intelligence capabilities. It shouldn't take eight months after Canada figures it out and probably a year after South Korea figures it out. Far after data reaches similar conclusion on a known carcinogen. I mean we are not the legislative committee. We are just the oversight committee, but we all serve on the committee that has legislative authority. What else can you offer us that you haven't already in terms of what we need to do?

Mr.WILLIAMS. Well, I think just about everything in our 11 point program would—we feel it would be very—would take care of this.

Mr.WALDEN. All right.

Mr.WILLIAMS. As far as seafood, imported seafood. And I think another example would be Cambodia. When the European Union went over there and found they had no, absolutely no, safety standards at all and would not allow their shrimp into the European Union, we continued to accept them.

Mr.WALDEN. We did what?

Mr.WILLIAMS. The FDA allowed them into this country. Our imports went up most like the Pakistani issue.

Mr.WALDEN. See, that is encouraging. That is encouraging. We haven't touched on the issue of radiation in beef. Does somebody want to tackle that one? Because I hear a lot that, you know, that could actually eliminate a lot of the disease. Mr. Marler, would that help?

Mr.MARLER. Yes.

Mr.WALDEN. Should we be doing that?

Mr.MARLER. Yes.

Mr.WALDEN. Is there any consumer issue with that?

Mr.MARLER. I think the consumer issue with it, I think the science isn't there to support the fear, but there is a fear. But we——

Mr.WALDEN. Right.

Mr.MARLER [continuing]. Radiate a lot of products.

Mr.WALDEN. And the practical effect of that is what?

Mr.MARLER. None.

Mr.WALDEN. Other than that?

Mr.MARLER. I mean other than eliminating or certainly reducing pathogens. The gentleman who talked about, you know, getting corn out of his field and eating the way we ate in the '50s and '60s, those days are long gone.

Mr.WALDEN. Right.

Mr.MARLER. And I think when our food chain is longer and more complex we have to look at interventions to protect us from pathogens that change on a daily basis.

Mr.WALDEN. You know those days are long gone, but perhaps our inspection regime is still stuck there.

Mr.MARLER. I would agree with you on that.

Mr.WALDEN. It is sort of like a car in Cuba, you know, they have got the best mechanics in the world because they keep those 50-year-old cars running, and or more. Thank you, Mr. Chairman. I am going to yield back to get onto the next panel.

Mr.STUPAK. On your radiation this committee has a joint request in right with GEO just waiting for the report back. It is something that we have looked at as part of the total food safety issue.

Mr.WALDEN. Perfect. Thank you, Mr. Chairman.

Mr.STUPAK. Ms. DeGette, for questions.

Ms.DEGETTE. Thank you very much, Mr. Chairman. Mr. Williams, your testimony got me to thinking about something I say quite often in these hearings. And that is it seems—and I think the shrimp industry's probably one of the best examples of how our entire food—or actually all of our consumer goods including food. Thirty years ago most of that food was domestically produced, and now a huge percentage is coming from overseas. And I frankly think that is one of the main reasons why our oversight agencies, like the FDA and the USDA, have broken down, because they are being asked to inspect things that they weren't asked. Would you agree with that statement?

Mr.WILLIAMS. Somewhat, yes.

Ms.DEGETTE. In your industry, over the last say 30, 40 years, what is the percentage—how have you seen the percentage of imports change?

Mr.WILLIAMS. It is since—actually since the late '90s we have been losing——

Ms.DEGETTE. If you can move that microphone a little.

Mr.WILLIAMS. Since the late '90s we have been losing more market share, especially since 2000, because of we feel like the lack of inspection for the imports. These products—this product is allowed to come in and capture our market. We are down to about 10 percent of our entire market now. We feel like if those shrimp were inspected they would not be allowed to come into the Nation, because they are contaminated. They are contaminated with illegal antibiotics, and they shouldn't be in this market.

Ms.DEGETTE. And one reason why people are buying them is they are cheaper than domestically produced shrimp.

Mr.WILLIAMS. That is right.

Ms.DEGETTE. Correct? And I would assume your industry's position is they're cheaper because they are not raised under the same strict standards your industry sets forward, correct?

Mr.WILLIAMS. That is right. We are wild caught domestic industry. We can produce and compete with anyone in the world. We always have until they started breaking the rules. And that is what they have done is break the rules and put our industry in jeopardy. We have——

Ms.DEGETTE. And do you think that there is more consumer risks to these imported shrimp as well.

Mr.WILLIAMS. Oh, yes, definitely. I had a—and this may be extreme, but I had a gentleman—when we started this early on we filed these trade petitions against these countries, and one of them was because of the chemicals. I had a rep from a chemical company. He was a salesman for years and years. And he told me that some of these chemicals such as chloramphenicol you really don't want to touch this product without rubber gloves on.

Ms.DEGETTE. Great. Now, Dr. Greger, one thing. I hope no one asked this, and I apologize, in my absence. You—one thing that struck me about that really horrifying video is that the USDA inspectors were actually at that plant twice a day. I think they said what, 6:30 a.m. and 12:30 p.m. Were those inspectors on site?

Dr.GREGER. There have to be inspectors on site——

Ms.DEGETTE. OK.

Dr.GREGER [continuing]. One-hundred percent of the time inside on the line, but not necessarily off-line inspectors or in the holding pens or in that area. And that is why something like closed circuit television——

Ms.DEGETTE. Right.

Dr.GREGER [continuing]. Camera or random checks.

Ms.DEGETTE. But let me stop you right there.

Dr.GREGER. Yes.

Ms.DEGETTE. What were those inspectors doing the rest of the time between when they went out there?

Dr.GREGER. And so inspectors were either inspecting other plants or were inside.

Ms.DEGETTE. So those two inspectors—or however many inspectors there were, they weren't on that particular site all day long?

Dr.GREGER. That—there was one inspector came the same time, same two times every day, but I am not sure where that inspector was at other times. Whether they were at that plant or looking at other plants.

Ms.DEGETTE. I see. OK. We had been under the impression there were inspectors on site during the whole work day. That is not correct.

Dr.GREGER. There are USDA inspectors inside the plant watching the carcasses.

Ms.DEGETTE. But they are different inspectors?

Dr.GREGER. There are on-site inspectors and on-line inspectors.

Ms.DEGETTE. OK.

Dr.GREGER. Excuse me. And off-line inspectors. For a plant to operate there has to be someone—there has to be a federal inspector looking at the carcasses, but there does not necessarily have to be an inspector watching the unloading and treatment of the animals before slaughter.

Ms.DEGETTE. OK.

Dr.GREGER. They have a mandate to do that, but evidently they don't have the——

Ms.DEGETTE. The resources.

Dr.GREGER [continuing]. Personnel.

Ms.DEGETTE. But both you, and also Mr. Marler, said that you could solve some of these problems with technology. And I would suspect too, Mr. Williams, in the shrimp industry we are going to have to get—this is true. We have been doing all these consumer product hearings and food hearings, and I mean frankly our food inspection and consumer products inspection systems are completely broken. But there is also no way we could ever have enough of a budget for every single lot of meat or every single lot of shrimp to be inspected. So I think one of the challenges that we have to face, we are in the 21st century, is to find innovative testing that is like these video surveillance cameras and other types of testing. Wouldn't you agree with that, any of you?

Mr.WILLIAMS. I would agree, but also agree that it should begin in the exporting nations. That is where it should begin.

Ms.DEGETTE. Yeah. Well, the last I heard the U.S. Congress doesn't have very much jurisdiction over the Chinese food business. But if we can figure that out I think we will be a big step ahead.

Thank you so much, Mr. Chairman.

Mr.STUPAK. Well, thank you. That concludes all the questions for this panel. We want to thank this panel. Before we leave, you know, we learned a lot about—this is our fifth food safety hearing, and a lot about imports. And Richard Wilfong, who is a detainee from another department agency, ICE, the Immigration and Customs Enforcement, will be leaving us. And, Richard, I just want to thank you for all your work in helping us understand the import business as you do. It makes all of us members who ask questions—the brains behind the operation are really sitting behind us and helping us out. And that goes on both sides. We have got a great staff. So I want to compliment the staff before we dismiss this panel and before we call up our next panel. And thank you to this panel for all of your insight. Thank you.

Mr.WILFONG. Thank you. Thank you very much.

Mr.STUPAK. I will now call up our second panel of witnesses. On our second panel we have Mr. Gary M. Rodkin, Chief Executive Officer of ConAgra Foods. Mr. B. Keith Shoemaker, President and CEO of Butterball. Mr. Christopher D. Lischewski, President and CEO of Bumblebee Foods. Mr. Rick Ray, President and CEO of New Era Canning Company. Mr. David DeLorenzo, President and Chief Executive Officer of Dole Food Company. Mr. David A. Eisenberg, Chairman of ANRESCO Laboratories, and Dr. Robert E. Brackett, PhD., Senior Vice President and Chief Science Regulatory Affairs Officer at the Grocery Manufacturers Association.

I think we are just waiting for one more. OK.

[Witnesses sworn.]

Mr.STUPAK. You are now under oath, and we will begin opening statements. Please, limit it to 5 minutes. If you have a longer statement we will include it in the record.

Mr. Rodkin, we will start on my left, if you would like to start. I am going to ask you to pull that mic up. Pull it towards you. If

we get it closer we can hear it a little better. It is not the best system in this room. Thanks.

STATEMENT OF GARY M. RODKIN, CHIEF EXECUTIVE OFFICER, CONAGRA FOODS, INC.

Mr.RODKIN. Good morning, Mr. Chairman and members of the committee.

My name is Gary Rodkin, and I am the chief executive officer for ConAgra Foods. Thank you for the invitation to testify today about the safety of our Nation's food supply. I became ConAgra Foods' CEO in October of 2005, and during my tenure we have made food safety a top priority throughout our company. We fully agree with the committee's objective of ensuring that our Nation's food supply is among the safest in the world.

I am pleased to report back to the committee on progress made with our Peter Pan peanut butter since our vice president for operations testified before you in April of last year, and how we have responded to new challenges with other products. I want to assure you how seriously we take our food safety responsibilities, and that this is a top priority throughout our company. As the CEO of the company whose core mission is to provide the consumers with safe, nutritious and wholesome food, the very possibility that one of our products could cause anyone harm is the very last thing that I would want to happen. I want to reiterate how truly sorry we are for any harm that our recalled peanut butter or pot pie products may have caused any consumer.

Today I want to convey three main messages to the committee. One, ConAgra Foods has followed through on our commitments made here last spring regarding steps needed to resume production of our Peter Pan peanut butter by creating a state-of-the-art manufacturing facility in Sylvester, Georgia. In fact, that plant successfully resumed operations in August 2007. Two, ConAgra Foods addressed a completely different type of food safety concern with our Banquet and store brand pot pies in October 2007. We have since resumed operations after making enhancements to that product line. And three, ConAgra Foods has undertaken a complete revamping and modernization of our food safety practices companywide with the benefit of outside experts and the full commitment from all our food safety program managers. Our foremost goal is to prevent food safety problems from occurring, but should they ever occur we will continue to act quickly and responsibly to protect consumers and make any needed safety improvements.

Throughout this process we have cooperated with the committee's investigation and will continue to do so. We have provided the subcommittee with written testimony that contains additional detail on the first two product specific messages so I will not repeat those here. Rather, I would like to focus my time speaking to you directly on our final message regarding our companywide food safety modernization efforts. Namely, that ConAgra Foods is conducting a companywide upgrade of our food safety programs and will make continuous improvements to ensure that we provide safe food to consumers. As we reported to the committee last spring ConAgra Foods is committed to a companywide process to continuously improve our food safety programs starting with our hiring of

a new chief global quality officer and the establishment of a food safety advisory committee. We have since taken the process much further and have undertaken the following steps. First, we are making a major investment in facility upgrades and in hiring additional quality personnel throughout the company. Specifically we have earmarked millions of dollars in capital for our facilities for projects that will further enhance the safe manufacture of our products. We are also in the process of hiring an additional 250 quality personnel companywide primarily to support our enhanced food safety standards at our facilities. Second, we have made a major commitment to enhanced training in our food safety requirements for all of our plant personnel and suppliers. Specifically, in September of last year we convened a meeting of every plant manager and every quality manager at our headquarters facility in Omaha, which I attended, to launch an enterprise-wide set of food safety improvements. We are conducting continuous food safety and quality training for all plant employees companywide. We have also reached out to our co-packers and plan to hold a food and safety quality intervention event with all key supervisors and contract packers in the very near future. Finally, we are conducting continuous safety audits across all plants with a particular focus on one, incoming ingredient quality programs; two, allergen and sanitation programs; three, foreign material control programs; and four, overall infrastructure. By the end of the year we will have reassessed every HACCP plan across all of our platforms. We have also created within ConAgra Foods a new microwave center of excellence—center of expertise, and have begun a review of cooking instructions across all of our products.

In conclusion, we appreciate the committee's interest in food safety, and we fully support the committee's goals. At ConAgra Foods we have met the commitments we made to the committee last spring regarding the process to be followed before resuming operations of peanut butter manufacturing at our Georgia facility. We responded quickly to an unexpected outbreak related to our pot pies, and we are well into a companywide process to review and upgrade our food safety programs for our entire business.

I want to emphasize that these improvements are ongoing and will continue. I personally will ensure that we will continuously challenge and improve our food safety programs and make certain that food safety is the centerpiece of our corporate culture. Thank you.

[The prepared statement of Mr. Rodkin follows:]

STATEMENT OF GARY M. RODKIN

Good Morning Mr. Chairman and Members of the Committee. My name is Gary M. Rodkin, and I am the Chief Executive Officer (CEO) for ConAgra Foods, Inc. (ConAgra Foods). Thank you for the invitation to testify today about the safety of our nation's food supply. I became ConAgra Foods' CEO in October of 2005 and, during my tenure, we have made food safety a top priority throughout our company. We fully agree with the Committee's objective of ensuring that our nation's food supply is among the safest in the world.

ConAgra Foods is one of North America's leading packaged food companies, serving grocery retailers, as well as restaurants and other foodservice establishments. Popular ConAgra Foods consumer brands include: Chef Boyardee, Egg Beaters, Healthy Choice, Hebrew National, Hunt's, Marie Callender's, Orville Redenbacher's, PAM and many others, including Peter Pan and Banquet. We operate more than

100 manufacturing facilities in 30 states, as well as facilities in several international locations.

I am pleased to be able to report back to the Committee on progress made with our Peter Pan peanut butter since our Senior Vice President for Operations testified before you in April of last year, and how we have responded to new challenges with other products. I want to assure you how seriously we take our food safety responsibilities and that this is a top priority throughout our company. As the CEO of a company whose core mission is to provide consumers with safe, nutritious and wholesome food, the very possibility that one of our products could cause anyone harm is the very last thing that I would want to happen. I want to reiterate how truly sorry we are for any harm that our recalled peanut butter or pot pie products may have caused any consumer.

Today, I want to convey three main messages to the Committee. One, ConAgra Foods has followed through on our commitments made here last spring regarding steps needed to resume production of our Peter Pan peanut butter by creating a state-of-the-art manufacturing facility in Sylvester, Georgia. In fact, that plant successfully resumed operations in August 2007. Two, ConAgra Foods addressed a completely different type of food safety concern with our Banquet and store brand pot pies in October 2007. We have since resumed operations after making enhancements to that product line. And three, ConAgra Foods has undertaken a complete revamping and modernization of our food safety practices company wide, with the benefit of outside experts and the full commitment from all our food safety program managers. Our foremost goal is to prevent food safety problems from occurring, but should they ever occur, we will continue to act quickly and responsibly to protect consumers and make any needed safety improvements. Throughout this process, we have cooperated with the Committee's investigation and will continue to do so. Let me now describe these three points in greater detail.

1. ConAgra Foods has followed through on its commitments to this Committee by making its peanut butter manufacturing plant in Sylvester, Georgia a state-of-the-art facility before resuming operations in August 2007.

When ConAgra Foods testified before this Committee in April 2007, we committed to addressing the suspected causes of the contamination at our Sylvester, Georgia facility that manufactures Peter Pan peanut butter, and to implement significant changes in the plant, including new, state-of-the-art machinery, technology, and designs throughout the facility. We further committed, prior to resuming operations, to obtain an independent review by an expert third-party and seek the concurrence of the Food and Drug Administration (FDA) as to the adequacy of the measures implemented. We have met each of these commitments, and our Sylvester plant resumed operations in August 2007 as a state-of-the-art facility.

Specifically, with the assistance of our outside experts, we took the following steps:

a. We made a significant capital investment (approximately $40 million) to substantially upgrade the Sylvester facility. This included: (1) installation of a new roaster; (2) installation of a new roof; (3) physical separation and segregation of raw material and finished product areas and activities (each with dedicated employees and equipment) to minimize possible cross-contamination; (4) dedicated equipment wash rooms for raw and finished areas; (5) upgraded air flow systems; and (6) enhanced quality control systems supported by additional quality personnel.

b. We enhanced both the frequency and sensitivity of our environmental and finished product testing programs for this facility, and assigned responsibility for sample testing to an independent, accredited laboratory.

As we made these changes, we kept FDA informed of our progress. Once the plant was fully operational, FDA conducted a multi-day, on-site inspection of the Sylvester facility and was satisfied with the overall condition of the facility. We believe that we have created an industry-leading, state-of-the-art facility for manufacturing peanut butter. We have also used this process as a springboard to assess and improve our food safety operations throughout the company.

2. ConAgra Foods responded quickly to a government finding in October 2007 that its Banquet and store brand pot pies had been implicated in a salmonella outbreak and has implemented necessary steps to improve the safe consumption of this "ready-to-cook" product.

In October 2007, we faced a very different kind of food safety challenge with our Banquet and store brand pot pies produced at our Marshall, Missouri plant which manufactures, among other products, pot pies in the turkey, chicken and beef varieties. Unlike peanut butter which is sold to consumers as a "ready-to-eat" product, pot pies are sold to consumers as a "ready-to-cook" product, meaning the product needs to be fully cooked prior to consumption. This cooking process, whether in a conventional or microwave oven, further assures the safety of the product by effec-

tively killing any bacteria that may possibly be present. We were therefore surprised to learn from the United States Department of Agriculture (USDA) that this product line had been implicated in a salmonella outbreak.

Nevertheless, we responded quickly. We suspended our pot pie manufacturing and distribution operations immediately upon learning of the outbreak on October 8, 2007. We promptly commenced environmental sampling and testing within the plant, followed by our issuance of a consumer advisory and, ultimately, a voluntary recall of all of our Banquet and store brand turkey, chicken and beef pot pie products. All of these actions were taken in close cooperation with USDA's Food Safety and Inspection Service (FSIS), which has primary jurisdiction because these pot pies are meat and poultry-based.

Our investigation into the root cause started with extensive laboratory testing of both environmental and finished product samples. Each of our 577 environmental samples tested negative for salmonella. We also conducted 219 laboratory tests of our ingredients, which were also all negative. We undertook testing of 2968 samples of finished product, which yielded 17 positives for the outbreak strain. All of those positives related only to Banquet turkey pot pies from the production dates July 13, 2007 and July 31, 2007.

As noted, because pot pies are a "ready-to-cook" product, salmonella had never been deemed a "hazard" in the context of our Hazard Analysis Critical Control Points (HACCP) plans, and we believe this to be so throughout the industry. Following this incident, however, we revised our HACCP plans to recognize salmonella as a potential hazard and to require Certificates of Analysis from our suppliers demonstrating that all ingredients are free of salmonella. We also instituted finished product testing for salmonella by an independent laboratory. Finally, we have instituted a multitude of process and equipment changes at the plant.

Our investigation also led us to learn a great deal more about microwave ovens and to determine that consumers needed much clearer directions for use on the product labels. In particular, we learned there is both a greater variability in the performance of microwave ovens than we were previously aware, as well as a lack of full understanding with respect to microwave cooking efficacy. Consequently, we made major changes to our on-pack cooking instructions to address these learnings with considerable specificity. These changes include a more prominent statement on the front and side panels that the product "Must Be Cooked Thoroughly. See Back for Directions." In addition, we have devoted most of the back panel to step-by-step microwave cooking instructions that include: (a) minimum wattage for microwave ovens (1100 watts); (b) proper cooking time (4-6 minutes); and (c) consumer-friendly ways to know when the product is cooked thoroughly, such as the visual cue "Crust is golden brown and steam rises from filling." To reinforce these messages, we added safe microwave cooking guidance on our website, conducted a satellite media tour that encouraged news stations to carry a news feature that further educated consumers about safe cooking in microwaves, and provided further training on the subject to our consumer affairs representatives who field calls from consumers.

Moving forward, we have engaged the National Center for Food Safety Technology at the Illinois Institute of Technology (often referred to as the Moffett Center) to undertake cooking tests and research on the use of microwaves to cook frozen foods. We have also engaged the American Frozen Food Institute in the process and have urged the food industry as well as microwave manufacturers to address the cooking issues associated with microwave ovens through improved cooking instructions and clear information regarding microwave oven wattages.

Throughout the investigation, we were in constant communication with the USDA and the Centers for Disease Control and Prevention (CDC). We shared with them on a real time basis all of our test data and the results of our investigative efforts. We worked closely with USDA on improvements that needed to be made. With the concurrence of USDA, we resumed production of our Banquet brand pot pies in November, 2007.

Having now been involved in two very different food safety outbreaks, we are more determined than ever to follow through on our commitment to improve our systems company wide to ensure we are producing safe, wholesome, quality products, whether they are "ready-to-eat" or need to be further cooked by consumers.

3. ConAgra Foods is conducting a companywide upgrade of our food safety programs and will make continuous improvements to ensure we provide safe food to consumers.

As we reported to the Committee last spring, ConAgra Foods is committed to a company wide process to continuously improve our food safety programs, starting with our hiring of a new Chief Global Quality Officer and the establishment of a Food Safety Advisory Committee. We have since taken the process much further and have undertaken the following steps.

First, we are making a major investment in facility upgrades and in hiring additional quality personnel throughout the company. Specifically, we have earmarked millions of dollars in capital for our facilities for projects that will further enhance the safe manufacture of our products. We also are in the process of hiring an additional 250 quality personnel company wide, primarily to support our enhanced food safety standards at our facilities.

Second, we have made a major commitment to enhanced training in food safety requirements for all of our plant personnel and suppliers. Specifically, in September of last year, we convened a meeting of every plant manager and every quality manager at our headquarters facility in Omaha to launch an enterprise-wide set of food safety improvements. We are conducting continuous food safety and quality training for all plant employees, company wide. We have also reached out to our co-packers and plan to hold a food safety and quality intervention event with all key supervisors and co-packers in the very near future.

Finally, we are conducting continuous food safety audits across all plants, with a particular focus on: (1) incoming ingredient quality programs; (2) allergen and sanitation programs; (3) foreign material controls programs; and (4) overall infrastructure. By the end of this year, we will have reassessed every HACCP plan across all of our platforms. We have also created within ConAgra Foods a new Microwave Center of Expertise and have begun a review of cooking instructions across all products.

In conclusion, we appreciate the Committee's interest in food safety, and we fully support the Committee's goals. At ConAgra Foods, we have met the commitments we made to the Committee last spring regarding the process to be followed before resuming operations of peanut butter manufacturing at our Sylvester, Georgia facility. We responded quickly to an unexpected outbreak related to our pot pies. And we are well into a company wide process to review and upgrade our food safety programs for our entire business. I want to emphasize that these improvements are ongoing and will continue. I personally will ensure that we continuously challenge and improve our food safety programs, and make certain that food safety is a centerpiece of our corporate culture.

Mr.STUPAK. Thank you. Mr. Shoemaker, your testimony please.

STATEMENT OF B. KEITH SHOEMAKER, PRESIDENT AND CEO, BUTTERBALL, LLC

Mr.SHOEMAKER. Thank you, Mr. Chairman. I am Keith Shoemaker, Chief Executive Officer of the Butterball, LLC. Butterball was formed in 2006 when Carolina Turkey purchased the Butterball brand from ConAgra Refrigerated Food. Butterball is the best known brand in the turkey industry. Food safety is to be job one. Let me make it clear that the food safety investigation regarding salmonella in ConAgra turkey pot pies suggested that Butterball turkey was not the source of production contamination. I would like to clarify information reported in the media. No Butterball, LLC product has been recalled. Butterball complies with all USDA requirements. USDA food safety officers are present in Butterball facilities on a daily basis. However, my company does not rely on federal inspection to ensure the safety of our products. At Butterball we go beyond federal regulations by using the latest food safety technologies, comprehensive food safety practices and stringent microbiological surveillance.

Permit me to explain how our food safety practices apply to ingredients, cooking, packaging and handling. Our requirements include stringent food safety practices for the handling of raw materials. It is generally recognized that raw meat, especially poultry meat, may contain salmonella. Science states salmonella does not grow below 44 degrees Fahrenheit, and will not typically grow below 50 degrees. That is why Butterball monitors and controls the temperature of our meat to less than 40 degree Fahrenheit and the

room temperature to less than 44 degrees. This is a common industry practice to slow or stop the growth of bacteria in raw turkey. The fact that Butterball raw materials are received from one of our own slaughter and debone facilities allows us to assure temperature control throughout the supply chain. Serving to keep the level of bacterial growth at a minimum prior to meat being cooked. Data generated by USDA from Butterball facilities indicates a very low presence of salmonella. In fact, facilities supplying the raw product have been identified by FSIS as demonstrating the best control for salmonella. The turkey products supplied to ConAgra is fully cooked, ready to eat, cooked in a bag turkey logs. Cooked in a bag products are generally considered one of the lowest risk meat products. Possible contamination of the product after cooking is prevented by the fact that the product is protected from environmental exposure subsequent to cooking.

That should help explain why the investigations regarding the ConAgra recall found no data to support that Butterball turkey meat is the likely source of salmonella identified in the outbreak. The turkey log we provided to ConAgra was made from our own raw materials, stuffed into packaging material, thorough cooked to kill bacteria that may be present. By packaging prior to cooking we prevent possible contamination after cooking. The food safety investigation regarding the recall confirms the effectiveness of these systems. No salmonella of the type that contained within the pot pies has ever been found in a Butterball facility. With cooked in the bag product the cook step is critical to the safety of the product. To ensure maximum food safety USDA requires a minimum of 160 degrees Fahrenheit instantaneously. At Butterball we do more. Specifically, these turkey logs are exposed to 162 degrees Fahrenheit for between 15 to 20 minutes. Our ovens include four computerized temperature probes that provide continuous readout. A calibrated hand held thermometer serves to verify product temperature as well. After cooking the cooked in the bag log is then shielded in temperature controlled as long as we have it.

From the time the disease was first identified Butterball cooperated with ConAgra Foods and USDA in investigating the possible source of the salmonella. Between August and October of '07, USDA conducted three major reviews of the Jonesboro facility and ConAgra conducted two more. There were no significant food safety findings in any of these reviews.

In our own inquiry, Butterball conducted intense microbiological testing. Again, all results were negative. In short, at the conclusion of the investigations, logs were fully cooked and the product in the package was likely not the source of outbreak.

Mr. Chairman, we at Butterball are eager to take every practical step to assure food safety for our customers. We have worked cooperatively with this committee and all other investigators and highly respect the experts. We remain eager to continue such efforts in the interest of future food safety.

Finally, Mr. Chairman, I would like to thank the committee for its efforts to advance food safety and interest in learning about food science principals that guide our practices. We at Butterball would be pleased for you to tour one of our facilities to learn more about our operations. Thank you.

[The prepared statement of Mr. Shoemaker follows:]

STATEMENT OF KEITH SHOEMAKER

SUMMARY

1. BUTTERBALL TURKEY NOT IMPLICATED. The food safety investigations regarding Salmonella in ConAgra turkey pot pies suggest that the Butterball turkey ingredient in those pot pies was NOT the source of product contamination.

2. INGREDIENT CONTROL. The turkey log Butterball provided to ConAgra was made from our own raw turkey, controlled to keep the level of bacterial growth at a minimum prior to the meat being cooked. Butterball facilities supplying the raw product have been identified by FSIS (USDA) as category one—"demonstrating the best control for Salmonella."

3. SPECIAL PACKAGING. Cooked in bag products are considered one of the lowest risk meat products because cooking destroys pathogens and the product is not subject to environmental exposure subsequent to cooking.

4. FULLY COOKED. Butterball cooks its turkey log to a higher temperature and holds that temperature longer than food safety requirements. Elaborate monitoring systems assure adherence to Butterball procedures to destroy pathogens.

5. INVESTIGATIONS. The food safety investigations regarding the pot pie recall confirmed the effectiveness of these systems. Further, no Salmonella of the serotype that contaminated the pot pies has ever been found in a Butterball facility. Indeed, only once has that Salmonella serotype been found in turkey.

6. BUTTERBALL COOPERATION. Butterball thanks the committee for its attention to food safety and invites Members and staff to tour a Butterball facility.

TESTIMONY

Thank you Mr. Chairman. My name is Keith Shoemaker, and I am Chief Executive Officer for Butterball, LLC (Butterball). Butterball was formed in 2006 when Carolina Turkey of Mt. Olive, North Carolina, purchased the Butterball Brand from ConAgra Refrigerated Foods. Butterball produces over 1.4 billion pounds of turkey meat annually.

At the outset, permit me to make clear that the food safety investigation regarding Salmonella in ConAgra turkey pot pies suggests that the Butterball turkey ingredient in those pot pies was NOT the source of product contamination.

All Butterball products bear the mark of Federal Inspection, noting compliance with all United States Department of Agriculture (USDA) regulatory requirements. USDA Food Safety Officers are present in all Butterball facilities on a daily basis. However, my company does not rely on Federal Inspection to ensure the safety of our products. At Butterball, we go beyond federal requirements by using the latest food safety technologies, comprehensive food safety practices, and stringent microbiological surveillance.

Food safety is top priority at Butterball, and I would like to focus my remarks today on our food safety practices. With specific reference to the turkey product used in the ConAgra turkey pot pies, permit me to explain how our food safety practices apply to ingredients, cooking, packaging, and handling. That should help explain why the investigations regarding the ConAgra recall have found no data to support the Butterball turkey meat is a likely source of the Salmonella identified in the pot pie illness outbreak. In short, the turkey log we provided to ConAgra was made from our own carefully controlled raw turkey, thoroughly cooked to kill Salmonella and other bacteria that may be present and packaged prior to cooking to prevent possible contamination after cooking has made the product safe. The food safety investigations regarding the pot pie recall confirmed the effectiveness of these systems. Further, no Salmonella of the serotype that contaminated the pot pies has ever been found in a Butterball facility. Indeed, only once has that Salmonella serotype been found in turkey.

INGREDIENT CONTROL

Our requirements include stringent food safety practices for the handling of the raw materials. It is generally recognized that raw meat, especially poultry, may contain Salmonella. Scientific literature states Salmonella does not show growth below 44° F and will not typically grow below 50° F. That is why our company monitors and controls the temperature of the meat (<40F) and the room (<44F). This is a common industry practice and has been recognized to slow or stop growth of bacteria in raw turkey. The fact that Butterball raw materials are received from our own slaughter and debone operations allows us to assure temperature control

throughout the supply chain, serving to keep the level of bacterial growth at a minimum prior to the meat being cooked.

USDA data confirms the effectiveness of Butterball Salmonella control procedures. Raw materials coming from our own slaughter facilities undergo USDA Salmonella testing. Data generated from Butterball facility indicate a very low presence of Salmonella. In fact, facilities supplying the raw product have been identified by FSIS as category one—"demonstrating the best control for Salmonella."

SPECIAL PACKAGING

The turkey product supplied to ConAgra is fully cooked, ready to eat, cooked in bag turkey log. To make this product, raw turkey meat is stuffed into the log packaging material and fully cooked in steam ovens. Packaging material for the turkey log is of a special design to allow the product to be fully cooked in the packaging without disrupting package integrity. Thus, it is called cooked in bag product.

Cooked in bag products are generally considered one of the lowest risk meat products because pathogens (bacteria that cause illness) that may commonly be found on raw product are destroyed by cooking. Possible contamination of the product after cooking is prevented by the fact that the product is protected from environmental exposure subsequent to cooking. Listeria monocytogenes is generally considered the leading risk for environmental bacteria contamination from exposure after cooking.

FULLY COOKED

With the cooked in bag product, the cook step is critical to the safety of the product. The leading pathogen risk for raw poultry is Salmonella. All cook temperatures of products are targeted at reducing Salmonella 7 logs (a "log" is 10 organisms per centimeter squared; 7 logs is 10,000,000 organisms per centimeter squared). Studies conducted by industry, USDA, FDA, and other scientific bodies, both internationally and domestically, recognize this as the necessary safety level to destroy the maximum amount of organisms. To achieve a 7 log reduction in products like turkey logs, USDA requires a minimum of 160° F <1 min. At Butterball, we do more. We cook our turkey logs to a higher internal temperature for a longer period of time. Specifically, our turkey logs are exposed to 162° F for between 15–20 minutes. This extra time and temperature is actually destroying far more than 7 logs of Salmonella required.

To be sure we actually meet our cooking specifications, our ovens include four computerized temperature probes that provide continuous read-out. Alarms sound on the oven when all probes reach 162° F. A calibrated hand-held thermometer serves to verify product temperature, as well.

PRODUCT HANDLING

Immediately after cooking, the cooked in bag turkey log is then taken into coolers and chilled to the appropriate temperature and maintained at that temperature as long as we have it.

FOOD SAFETY INVESTIGATIONS

From the time the foodborne disease outbreak was first identified, Butterball cooperated with ConAgra Foods and USDA to investigate the possible source of the Salmonella. Several audits of records, facility, cooking, and food safety practices were conducted.

A review of the inspectional record was reassuring.

• August 2007—The Jonesboro facility had only recently undergone the USDA Food Safety Assessment, completed, with no major finding.

• October 6, 2007—USDA came back into the facility for another review, again with no findings reported.

• October 25, 2007—USDA took fifteen microbiological swabs of the processing environment, all reported negative for the presence of the Salmonella.

In our own inquiry, Butterball conducted intensified microbiological testing including turkey logs ready for shipment, combo bins used for shipping the log and the trailers used for shipping again, all results were negative.

A ConAgra review team came to the facility October 14 and 15 to review records and production practices. No adverse findings were identified. On October 31 another team of ConAgra representatives, including outside experts, came to the facility to further investigate production practices associated with the oven operation. Butterball routinely calibrates the ovens and shared this information and the finding with the ConAgra review team. Again, there were no adverse findings noted.

Additionally, at the request of ConAgra, a third party went into Jonesboro and validated each oven in the facility. The results of the third-party testing indicated that the ovens were functioning as they should, and the cooking cycles were far exceeding the lethality targets outlined in the food safety plan.

Finally, a review of Salmonella testing data serotypes from USDA illustrates that no Salmonella of the serotype that contaminated the ConAgra turkey pot pies (Sal-

monella I 4,[5],12:i:-) has ever been identified in a Butterball facility. Scientific literature available on this particular serotype notes it is commonly associated with chickens. USDA data shows only one incident of this serotype in turkey over several years of testing. That was not a Butterball turkey.

In short, the conclusion of the investigation: the logs were fully cooked, and the product in the package was likely not the source of the outbreak.

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Mr. Chairman, we at Butterball are eager to take every practical step to assure food safety for our consumers. We have worked cooperatively with this committee and all other investigators and highly respected experts. We remain eager to continue such efforts in the interest of further improving food safety.

Finally, Mr. Chairman, I would like to thank the committee for its efforts to advance food safety and interest in learning about the food science principles that guide our practices. We at Butterball would be pleased for you to tour one of our facilities to learn more about our operations.

Thank you.

Mr.STUPAK. Thank you. Mr. Lischewski.

STATEMENT OF CHRISTOPHER D. LISCHEWSKI, PRESIDENT AND CEO, BUMBLE BEE FOODS, LLC

Mr.LISCHEWSKI. Mr. Chairman and members of the committee, my name is Chris Lischewski, President and CEO of Bumblebee Foods and Castleberry's Food Company.

I appreciate the opportunity to be here today to provide my testimony and to respond to the committee's questions related to the recall of canned products of Castleberry's Food Company due to the risk of botulism contamination.

First, I would like to say that we are in the business of providing wholesome food products to the public and making sure that our food is safe is always our first priority. Previously food that had to be recalled was the worst thing we could have faced, and we deeply regret that it occurred. We have tried to deal with the situation in a manner that reflects our sense of responsibility, our understanding of the gravity of the situation, our desire to make whole all the purchases of our recalled products and our continuing commitment to ensuring that all of our products are safe for consumers.

Upon learning of possible botulism contamination from FDA and the CDC Castleberry's immediately instituted a voluntary recall of 10 products. To further minimize the risk to public health we quickly expanded the recall to extend beyond the specific products and production dates linked to apparent cases of illness. And ultimately our product recall included over 90 products produced over a two year period. We also voluntary ceased production at our operating facility in Augusta. We informed the public about the recall through extensive public awareness programs in both English and Spanish. Frequent press releases and advisories were issued and multiple press conferences were held. The consumer hotline was established and staffed around the clock with call center professionals. Our website was updated. Advertisements ran in regional and national newspapers, direct mailing were sent to consumers and warnings were even printed on cash register receipt printouts. And including and in addition to that we engaged in numerous interviews with the media. As of October of last year there had been nearly 5,000 broadcast stories on the recall, in large part generated by the company to drive public awareness. And we also

made it very easy for consumers to obtain refunds. No proof of purchase or return of product was required, and we just trusted the people to be honest with us.

Retrieving recalled products in the marketplace was a large task, and we mobilized vast resources. I believe both FDA and USDA will confirm that we did everything they asked of us and more in order to notify retailers and consumers of the recall, and to quickly and safely remove product from the shelves. Upon announcement of the recall we immediately began by telephoning and e-mailing the contacts of all of our direct retail customers who had purchased any of the recalled products at any time during the previous two years. In addition to these ongoing telephone calls we sent nine company bulletins to these customers between July 18 and August 15 to update them on the recall. In addition to our direct contact to retail customers we engaged a company called RMX to physically visit 18,619 stores during the 10 day period following the recall to confirm removal of the product from the store shelves. And we followed that up with another company called RMX to over the next 60 days to cover 22,000 stores again. In less than one percent of the stores visited were recalled products on the shelf. We worked with customers that had loyalty card programs to send letters directly to consumers who had purchased recalled products. And, again, also engaged Catalina Marketing to run a program where by consumers who had previously purchased any recall product would receive on their register tape with the next purchase a warning notifying them of the recall.

Throughout the recall we were in constant communication with the regulatory agencies establishing a daily conference call during the first few weeks of the recall to keep the agencies apprised of our efforts, to seek their input, and to provide answers to their questions. We also engaged an experienced consultant to advise us in any additional measures we might take. We worked openly and diligently to cooperate with FDA, USDA and this committee to facilitate all investigations including granting interviews and providing all documents requested. Together with processing authorities and regulatory experts we conducted an extensive, intensive investigation and identified the cause of the contamination. We have taken effective steps to prevent an occurrence and have also taken the opportunity to elevate our safety practices and procedures to an even higher level. In addition, we completed independent third party audits at all of our other facilities to ensure that appropriate procedures are in place.

I truly appreciate the opportunity to come before you to discuss the recall, and hope that this can be a learning experience for all those involved in the industry where we work together to ensure that these types of incidents never happen again. Thank you.

[The prepared statement of Mr. Lischewski follows:]

STATEMENT OF CHRIS LISCHEWSKI

I'm Chris Lischewski, President and CEO of Bumble Bee Foods and Castleberry's Food Company. I appreciate the opportunity to be here today to provide my testimony and to respond to the Committee's questions related to the recall of canned products by Castleberry's Food Company due to the risk of botulism contamination.

First, I would like to say that we are in the business of providing wholesome food to the public. Making sure that our food is safe is always our first priority. Pro-

ducing food that had to be recalled was the worst thing we could have faced, and we deeply regret that it occurred. We have tried to deal with the situation in a manner that reflects our sense of responsibility, our understanding of the gravity of the situation, our desire to make whole all of the purchasers of our recalled products, and our continuing commitment to ensuring that all of our products are safe for consumers.

Upon learning of possible botulism contamination from FDA and CDC, Castleberry's immediately instituted a voluntary recall of ten products. To further minimize the risk to the public health, we quickly expanded the recall to extend beyond the specific products and production dates linked to apparent cases of illness. Ultimately, over ninety products produced during a two-year period were recalled. The factory voluntarily ceased all production and distribution.

We informed the public about the recall through an extensive public awareness program in both English and Spanish. Frequent press releases and advisories were issued, multiple press conferences were held, a consumer hotline was established and staffed around the clock with call center professionals, the Castleberry's website was regularly updated (in both English and Spanish), advertisements ran in regional and national newspapers, direct mailings were sent to consumers, warnings were printed on cash register receipt print outs, and we engaged in numerous interviews with the news media. As of October of last year, there had been nearly 5,000 broadcast stories on this recall in large part generated by the company to drive public awareness. Also, we made it very easy for consumers to obtain refunds-no proof of purchase or return of product was required. We trusted people to be honest with us.

Retrieving the recalled product from the marketplace was a large task, and we mobilized vast resources. I believe FDA and USDA will confirm that we did everything they asked of us, and more, in order to notify retailers and consumers of this recall, and to quickly and safely remove products from store shelves. Upon announcement of the recall, we immediately began, by telephone and e-mail, to contact all of our direct retail customers who had purchased any of the recalled products at any time during the previous two years. In addition to these ongoing personal telephone calls and emails, we sent nine company bulletins to these customers between last July 18 and August 15, to update them on the recall and to provide additional information on things such as procedures for product retrieval and destruction. We engaged a contractor to retrieve and dispose of recalled product to avoid it being returned to the factory or to any of our distribution centers.

In addition to our direct contact with our retail customers, we engaged a company called RMX to physically visit 18,619 stores during the ten-day period following commencement of the recall, to confirm removal of recalled product from store shelves. Then, as a follow-up to the RMX visits, we engaged the CORE retail team division of Advantage Sales & Marketing to further assess the effectiveness of the recall by visiting more than 22,000 stores during the next 60 days. In the less than 1% of the stores visited where recalled product was found on a shelf, the CORE team worked with the stores to dispose of the product. We worked with customers that had loyalty card programs to send letters directly to consumers who had purchased recalled products. We also engaged Catalina Marketing to run a program at approximately 22,000 stores whereby consumers who had previously purchased any recalled product would receive on their register tape, at their next purchase, a warning notifying them of the recall and directing them to our website and hotline. Throughout the recall, we were in constant communication with the regulatory agencies, establishing a daily conference call during the first few weeks of the recall to keep the agencies apprised of our efforts, to seek their input and to provide answers to their questions. We also engaged an experienced consultant to advise us on any additional measures we might take. We did everything we reasonably could to get the recalled products off of store shelves and out of consumers' kitchens.

We worked openly and diligently to cooperate with FDA, USDA, and this Committee to facilitate all investigations, including granting interviews and providing all documents requested. Together with processing authorities and regulatory experts, we conducted an intensive investigation and identified the cause of the contamination. We have taken effective steps to prevent a recurrence, and have also taken the opportunity to elevate our safety practices and procedures to an even higher level. We also completed independent third-party audits at all of our other facilities, to ensure that appropriate safety procedures are in place.

Following the completion of our investigation and implementation of improved preventative safety procedures, we prepared submissions to USDA and FDA documenting the findings of our investigation and seeking their approval of our plan to re-open the facility. Our SVP of Technical Services and other management from Augusta met with FDA officials in Washington on September 5, 2007, to discuss our

submission and to address any questions or concerns. At FDA's request, we set up a conference call the next day with our process authority to address FDA's questions. We received approval to re-open from FDA on September 12th and from USDA on September 14th. On September 17th, the plant re-opened. The line on which the recalled product was manufactured is not and will not be run until a further in-depth review has been completed and additional operational control systems have been reviewed for possible installation to provide more robust operating and monitoring systems for these complex retorts.

I want to reiterate our deepest regret that this incident occurred. Consumer safety is of the utmost importance to our company and to its employees, including me. We have taken, and continue to take, this matter extremely seriously and personally. As we try to move forward from this experience, we do not forget those who were most affected. We are working with those individuals who contracted botulism to resolve their claims in a fair and amicable manner.

I truly appreciate this opportunity to come before you to discuss the recall, and I hope that this can be a learning experience for all those involved in the industry as we work together to ensure that these types of incidents never happen again.

Thank you.

Major Points:

- Upon learning of possible botulism contamination from FDA, Castleberry's immediately instituted a voluntary recall, which was quickly expanded to extend beyond the specific products and production dates linked to apparent cases of illness, in order to minimize any potential risk to the public. The factory was voluntarily shut down.
- With the assistance of a team of process authorities and regulatory experts, Castleberry's conducted an intensive investigation and has identified the cause of the contamination, has taken effective steps to prevent a recurrence, and has taken the opportunity to elevate its safety practices and procedures to an even higher level. Bumble Bee initiated independent third party-audits of all of its other facilities. Those audits were all successfully completed last year, with no issues of significance.
- Following the completion of our investigation, we worked together with FDA and USDA to obtain their approval to re-open the plant (other than the line on which recalled product was produced.
- Castleberry's worked diligently to cooperate with FDA, USDA and this Committee to facilitate all investigations, including granting interviews and providing documents.
- Castleberry's has gone beyond what was required by FDA, USDA and state agencies to ensure an effective recall. Efforts included website communications (both Spanish and English), media coverage (press releases, advertisements, press conferences and media interviews), customer calls, direct mailing to consumers, RMX/ASM-CORE retail coverage, Catalina program, third-party product retrieval/destruction service.
- Refunds were made easily available for consumers via our website without requiring return of product.
- Castleberry's is working with consumers who claim they contracted botulism from recalled products to resolve the claims.

Mr.STUPAK. Thank you.

Now, Mr. Ray, your testimony, please.

STATEMENT OF RICK RAY, PRESIDENT AND CEO, NEW ERA CANNING COMPANY

Mr.RAY. Good afternoon, Mr. Chairman and members of the committee. My name is Rick Ray and I serve as president of the New Era Canning Company. Thank you for your invitation to testify today.

New Era Canning Company is a small fourth generation family owned fruit and vegetable canning operation located in New Era, Michigan. For the past 98 years New Era Canning has been serving customers in the retail and food service industry with high quality canned fruits and vegetables. The New Era name is not widely known because we serve primarily the private label or store

brand market. We operate a single facility and employ 50 full-time people as well as 100 to 200 seasonal employees during our processing seasons. We process asparagus, green beans, wax beans, applesauce, sliced apples, pumpkin and a variety of dry bean items.

We have a long tradition of providing safe food products to our customers. We fully realize that we are accountable for every case of canned food that we produce. We take that responsibility seriously. Today New Era's in the midst of a recall of our low acid canned vegetable products. The reason is that FDA discovered C. botulinum spores in New Era's canned vegetables.

In New Era's 98 year history we have never previously experienced anything such as this. Permit me to explain what my scientific experts have told me about the classic concern regarding the C. botulinum contamination of canned foods, especially low acid canned foods. C. botulinum spores are ubiquitous. They originate in soil and, therefore, they are all around us. The spores are not harmful, but in the proper environment they can produce C. botulinum toxin which is highly toxic. In simple terms we are prudently assuming that C. botulinum spores will be naturally present in canned vegetable products. Thus, the most important step in canning is to bring the canned product to a sufficiently high temperature to kill the C. botulinum spores. Then to prevent overcooking the canned vegetables the cans are promptly cooked using water. The classic C. botulinum problem in canned vegetables occurs when some part of the product does not reach a killing temperature. In that situation the spores have been shocked, but not killed by the cooking. The shock to the spores prompts them to start growing and producing toxins. Unfortunately, low acid canned foods are a suitable environment for the growth of C. botulinum spores and the production of toxin.

While our investigation is still under way and we have not yet received key information from the FDA about their findings, our scientific experts tell me that it appears that the classic C. botulinum situation is not what occurred at New Era. In the extensive sampling of New Era production, most of which we had on hold due to production irregularities, the C. botulinum spores, but not toxin was found. At least to date the C. botulinum found appears not to be a result of insufficient canning temperature to kill C. botulinum spores. Instead, it appears the presence of C. botulinum spores, but not toxin, in New Era canned vegetables is due to the entry of spores into cans during the cooling of the product after the can has been sealed and the product cooked. If the can seam is not to specification or becomes damaged microscopic—of cooling water can enter the can. This is why the industry has long used only safe drinking water in the can cooling.

There are several reasons why this is the leading theory for the presence of C. botulinum in New Era canned vegetables. First, FDA tests of drinking water wells used by New Era for cooling water found that C. botulinum spores were present in the water. Second, the New Era processes that produced the contaminated product appear to have been achieving appropriate canning temperatures. Third, the presence of C. botulinum spores, but not toxins, suggests that the spores were not shocked by cooking tempera-

tures, which corresponds with the theory that the introduction of the spores was in the cooling water.

In the scant scientific literature on the subject C. botulinum spores are regarded as so unlikely to be found in water that testing is not a standard procedure.

Mr. Chairman, the investigations, however, are still under way, so this conclusion must be regarded as preliminary. The FDA investigation of our company began 11 weeks ago. Working with technical experts we are addressing all issues raised by the FDA, as well as investigating additional opportunities to improve our overall operation. While it appears that the spores that entered New Era products in this manner have not been shocked and did not produce toxin, that fact is not satisfactory to New Era, and for that matter the FDA. No C. botulinum spores that have the capacity to produce toxins should ever be present in our products.

This has been a resource intensive and difficult process for New Era to experience. But it is our intent to determine the cause of the current problem and to take whatever measures are necessary to ensure a safe product. We are very thankful that, to the best of our knowledge, there have been no reported illnesses from any of our canned vegetables. Again, we are and always have been committed to our responsibility to produce safe and wholesome products. Thank you.

[The prepared statement of Mr. Ray follows:]

Testimony by Rick Ray
President, New Era Canning Company
Before the Subcommittee on Oversight and Investigations,
Committee on Energy and Commerce,
U.S. House of Representatives
February 26, 2008

Good Morning, Mr. Chairman and Members of the Committee. My name is Rick Ray and I serve as the President of New Era Canning Company. Thank you for your invitation to testify today.

New Era Canning Company is a small 4th generation family-owned fruit and vegetable canning operation located in New Era, Michigan. For the past 98 years, New Era Canning has been serving customers in the retail and foodservice industry with high quality canned fruits and vegetables. The New Era name is not widely known because we primarily serve the private label or "store brand" market. We operate a single facility and employ 50 fulltime employees and between 100 and 200 seasonal employees during our processing seasons. We process asparagus, green beans, wax beans, applesauce, sliced apples, pumpkin and a variety of dry bean items.

We have a long tradition of providing safe food products to our customers. We fully realize that we are accountable for every case of canned food that we produce. We take that responsibility seriously.

Today, New Era is in the midst of four recalls of our low acid canned vegetable products. The reason for these recalls is that FDA discovered *C. botulinum* spores in

New Era canned vegetables. In New Era's 98 year history, we have never previously experienced anything such as this.

Permit me to explain what my scientific experts have told me about the classic concern regarding *C. botulinum* contamination of canned foods, especially low acid canned foods. *C. botulinum* spores are ubiquitous; they originate in soil and are therefore all around us. The spores are not harmful, but in the proper environment they can produce *C. botulinum* toxin, which is highly toxic. In simple terms, we prudently assume that *C. botulinum* spores will be naturally present in canned vegetable products. Thus, the most important step in canning is to bring the canned product to a sufficiently high temperature to kill the *C. botulinum* spores. Then, to prevent "overcooking" the canned vegetables, the cans are promptly cooled using water.

The classic *C. botulinum* problem in canned vegetables occurs when some part of the product does not reach a killing temperature. In that situation, the spores have been "shocked," but not killed by the cooking. The "shock" to the spores prompts them to start growing and producing toxin. Unfortunately, low acid canned foods are a suitable environment for growth of the *C. botulinum* spores and the production of toxin.

While our investigation is still underway and we have not yet received key information from the FDA about their findings, our scientific experts tell me that it appears the classic *C. botulinum* situation is <u>not</u> what occurred at New Era. In the extensive sampling of suspect New Era production, most of which we had on hold due to

production irregularities, *C. botulinum* spores, but not toxin was found. At least to date, the *C. botulinum* found appears not to be a result of insufficient canning temperature to kill *C. botulinum* spores. Instead, it appears the presence of *C. botulinum* spores, but not toxins, in New Era canned vegetables is due to entry of the spores into the cans during the cooling of the product, after the can has been sealed and the product cooked.

If the can seam is not in specification, or becomes damaged, microscopic amounts of the cooling water could enter into the can. This is why the industry has long used only safe drinking water for its can cooling.

There are several reasons why this is the leading theory for the presence of *C. botulinum* in New Era canned vegetables. First, FDA tests of the drinking water wells used by New Era for cooling water found that *C. botulinum* spores were present in the water. Second, the New Era processes that produced the contaminated product appear to have been achieving appropriate canning temperatures. Third, the presence of *C. botulinum* spores, but not toxins, suggests that the spores were not "shocked" by cooking temperatures, which corresponds with the theory of the introduction of spores in cooling water.

In the scant scientific literature on the subject, *C. botulinum* spores are regarded as so unlikely to be found in water, that testing is not a standard procedure. Mr. Chairman, the investigations, however, are still underway, so this conclusion must be regarded as preliminary.

The FDA investigation of our company began 11 weeks ago. Working with technical experts, we are addressing all issues raised by the FDA, as well as investigating additional opportunities to improve our overall operation.

While it appears that the spores that entered New Era products in this manner were not "shocked" and did not produce toxins, that fact is ***not*** satisfactory to New Era or, for that matter, FDA. No *C. botulinum* spores that have the capacity to produce toxin should ever be present in our products.

This has been a resource-intensive and difficult process for New Era to experience, but it is our intent to determine the cause of the current problem and take what ever measures are necessary to ensure a safe product.

We are very thankful that, to the best of our knowledge, there have been no reported illnesses from any of our canned vegetables and again, we are, and have always been committed in our responsibility to produce safe and wholesome products.

Thank you.

Mr.STUPAK. Thank you. Mr. DeLorenzo.

STATEMENT OF DAVID A. DELORENZO, PRESIDENT AND CHIEF EXECUTIVE OFFICER, DOLE FOOD COMPANY, INC.

Mr.DELORENZO. Thank you, Mr. Chairman. Is that on?

Mr.STUPAK. Yes, it is. It sounded good.

Mr.DELORENZO. OK. Thank you again, Mr. Chairman and members of the subcommittee.

My name is David DeLorenzo and I am the CEO of the Dole Food Company residing in Westlake Village, California.

Our mission at Dole is to provide healthy, nutritious products to consumers. Food safety and consumer confidence in the safety of the food chain is not only vital to the mere existence of our firm, but we believe to the health of the Nation. We are pleased to participate in this hearing, and any other forums that might work toward ensuring food safety and with it the dietary habits of America.

I would like to address the two vegetable recall events that touched our vegetable division during the past two years, and the steps that we and industry have taken to respond to those food safety incidents. First was the industry-wide halt of all spinach sales that occurred in September of 2006, after Natural Selection Foods recalled all packaged fresh spinach that it has produced and packaged. These packages were sold under 28 different brand names, one of which was ours. Our name was on the product, but it was produced and packaged by Natural Selection Foods, a highly regarded company that I believe has already testified before this subcommittee. Dole did perform regular audits of their operations and accepted the product into the Dole label and responsibility for their good practices. Dole has no ownership or other economic interest in Natural Selection Foods. Federal and state regulators reported that the source of the problem came from a specific spinach farm that was being farmed organically. At that time Dole did not internally farm or package spinach. We did not have the necessary specialized machinery to produce spinach and, therefore, had contracted with Natural Selections Foods to produce and package these products for us. Since that time we have invested in the machinery to package spinach and other tender leaf products ourselves, and are in the process of moving all of this activity under our own farming and into our own plants.

The other incident I wish to address involved the recall of some of our salad product in Canada in September of 2007. On September 14 the Canadian Health Ministry told us that they had randomly pulled a number of bags of our salad from a store shelf in Canada, and that one had tested positive for E. coli. We immediately announced a recall. None of the other Canadian bags, nor any other bags of the same production batch that we had retained, nor any of the bags turned in by consumers tested positive for E. coli or any other pathogen. Our processing plant and the farms in which the produce was grown were carefully inspected by Canadian, U.S. federal and state regulators, and there is nothing negative to report there either. More significantly, there were no illnesses reported that were associated with this product in Canada

or the United States. The source of this incident, unfortunately, remains a mystery, which is disconcerting and I believe unacceptable.

And I will second what was said earlier in testimony, and I would recommend later in my testimony the urgent need for more research about bacteria, E. coli 157. I'm sorry, 155. Despite the need for more research I do believe that the reaction to this spinach problem by the industry and Dole was swift and did show an unprecedented commitment to food safety. The leafy greens industry in California studied, prepared and adopted the Leafy Greens Marketing Agreement within four months of inception. The backbone of the program is mandatory testing and audits by California state inspectors using such food safety metrics as irrigation water tests, employee hygiene, harvesting equipment sanitation, buffer zones, soil amendments, wildlife intrusion and previous land use. We have taken a leading role in this statewide initiative and remain part of its ongoing board. We are now working with the Arizona industry to establish a similar agreement. Dole supports national regulatory food safety standards for all fresh produce items, and the California and Arizona programs could be the starting point toward designing and implementing these standards for both domestic and imported items. As a company Dole fresh vegetables has undertaken some key initiatives aimed at providing a higher level of food safety. First is our implementation of a trace back system that is RFID driven. RFID stands for radio frequency identification. This process involves placing a unique tag on every bin of lettuce harvested in the field. The tag is scanned using the global positioning system so that there is a tracking record of where in the field the product originated, how far and how long it traveled after that and how soon each bin was cooled and processed. RFID tracking is not a firewall for food safety. It does, however, provide real time field locations to within approximately 100 feet of where the product was harvested in the even trace back is needed. The inability to quickly trace back to a specific field location hampers the ability to determine the root cause of a problem, and has been a major impediment to regulatory investigators, not because our industry is unwilling, but because the technology available until now was not adequate as we mentioned earlier.

In addition Dole and its growers have implemented testing for pathogens in the field prior to harvest, as well as testing at our produce centers, our processing plants and as it leaves a spinach product. Since the spinach incidences we have completed approximately 4,000 of these tests for pathogens. Thus far we have not had any positive tests for pathogens.

Other Dole fresh vegetable risk reduction activities include a full-time staff of quality assurance and food safety specialists. All of our fields in California are irrigated by water from deep wells or city water. We test the wells once a month during the growing seasons when the water is used. We will not grow, harvest or purchase crops from fields that get flooded with run off from other fields, let alone from cattle pastures, nor from fields that are too close to a place where cattle have been. We also contract with third party food safety companies to supplement our auditing processes in addition to the state inspectors that are part of the California Leafy Greens Agreement. All of our salad processing plants have full-time

quality assurance staffs on site, and all operate under a defined HACCP plan, and our fields operate under defined GAP or Good Agriculture Practices plan, as well as the leafy greens audit.

The produce industry needs to continue to move forward with refining agricultural practices as science and technology advance. We need government support for more research activities in understanding how pathogens survive and migrate in the natural environment, especially E. coli. We also need research in developing microbial kill steps that will work on a perishable product. The amount of research needed is significant in both time and dollars. Dole supports standardized regulations in the food industry to ensure food safety. Food safety begins at the farm and continues through the supply chain to manufacturing plants, transportation, handlers, retail outlets and the hands and homes of the consumer. We encourage and support efforts to establish industry-wide protocols and procedures, as well as consumer education. Due to the perishability of fresh produce and the exactitude necessary for proper laboratory testing we would encourage all funding necessary for the state-of-the-art laboratories that can provide quick turn around of tests with exactitude of findings.

Private companies such as Dole will continue to accelerate and champion new practices and technologies aimed at eliminating food safety risks. Produce is a living, breathing organism grown for the most part in the open air that requires specialized care. It will continue to take a concentrative and significant effort in time, funding and regulation from both the government and the private sector to make our food system, already the safest in the world, even safer. We commit ourselves to work with your subcommittee and help in any way possible with improving future food safety regulation. Thank you.

[The prepared statement of Mr. DeLorenzo follows:]

STATEMENT OF DAVID A. DELORENZO

Two E. coli recall events touched our Vegetables Division during the last two years:

1. September 2006 industry-wide halt of all spinach sales, after Natural Selection Foods LLC recalled packaged fresh spinach it had produced and packaged. These packages were sold under 28 different brand names, one of which belonged to Dole. Dole has no ownership or other economic interest in Natural Selection Foods. The source of the problem appeared to be in a spinach farm field, owned by a reputable grower, that was being farmed organically.

2. September 2007 recall of some of our salad product in Canada. Canadian Health Ministry told us that a bag of our salad randomly picked from a store shelf in Canada had tested positive for E. coli. None of the other Canadian bags, nor any other bags of the same production batch, nor any of the bags turned in by consumers, tested positive for E. coli. Our processing plant and the relevant farms were inspected by Canadian, US Federal and State regulators—no problems were found. More significantly, no illnesses were reported that were associated with this product in Canada or the United States.

Responses to the 2006 spinach issue: The California Leafy Greens Marketing Agreement, covering 99% of California leafy greens handlers, was implemented. The backbone of this Agreement is mandatory testing and audits by California state inspectors using such food safety metrics as: irrigation water tests, employee hygiene, harvesting equipment sanitation, buffer zones, soil amendments, wildlife intrusion, and previous land use. Our Vegetables' division President sits on the governing boards of both the California and the proposed Arizona programs.

We view these industry programs as only a starting point. Dole supports national regulatory food safety standards for all fresh produce items.

Dole has made significant investments in developing and applying RFiD technology to leafy greens; we have made this program available to the all companies in the industry, without any payment whatsoever to Dole. RFiD tracking allows trace-back to within approximately 100 feet of where the produce was harvested. The inability to quickly trace back to a specific field location has been a major impediment to regulatory investigators, until now.

We have implemented testing for pathogens in the field prior to harvest; we also test produce as it enters our processing plants and as it leaves as finished product. We have completed approximately 4,000 of these tests for pathogens. Thus far we have not had any positive test results for pathogens.

We need government support for more research activities in understanding how these pathogens survive and migrate in the natural environment, as well as in developing microbial kill steps that will work on perishable produce. The amount of research needed is significant in both time and dollars. We believe that the federal agency best suited to oversee this research effort is the USDA. We also encourage more funding for state-of-the-art laboratories that can provide quick turn around of tests with exactitude of findings.

STATEMENT

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, my name is David DeLorenzo and I became the CEO of Dole Food Company, Inc. last June, having worked for Dole for the last 37 years. Thank you for allowing Dole the opportunity to be a part of the ongoing discussions on food safety.

Our mission at Dole is to provide healthy, nutritious products to consumers. Food safety, and consumer confidence in the safety of the food chain, is not only vital to the mere existence of our firm, but, we believe, to the health of the Nation. We are pleased to participate in this hearing and in any other forums that might work toward ensuring the safety of the food chain and with it the improved dietary habits of our constituents.

We take great pride in our people, the quality of our products and our commitment to Corporate Social Responsibility, including food safety, the environment, and the welfare of our workers. We also believe in transparency, and welcome any audits and scrutiny of our own operations and that of the industries in which we operate, to ensure that we and others in the industry are doing everything possible to deliver healthy, safe products to the consuming public. Toward that end, we would certainly welcome and encourage any Member of this Subcommittee and its staff to please come and visit any of our operations, to see our farms, refrigerated supply chain and manufacturing plants. Our salad manufacturing plants are in California, Arizona, Ohio and North Carolina, but we source from most of the fruit and vegetable growing areas in the United States, including California, Arizona, Oregon, Washington, Michigan, Texas, Colorado and Florida, to mention a few. Being this diverse requires us to establish strict and important relationships with farmers across a wide spectrum of crops who join us in adhering to good agricultural practices and strict protocols.

We have been around as a company for more than 150 years, and we always are willing to exchange views and share our experience. The work this Subcommittee is doing is vital to our Nation, and to our industry, and we want to help in any way we can.

Dole Fresh Vegetables is one of our divisions in North America; it is headquartered in Monterey, California. This is our division that has been affected by two E. coli recalls in the last two years. As I will discuss in a minute, in the first of these recalls, our name was on the product but it was produced and packaged for us by an unrelated, but highly-regarded company that has an excellent name in the production of spinach and tender leaf salads and in organic salads. In the more recent and much smaller recall, originating in Canada, one bag of our salad, pulled at random from a store shelf in Canada, tested positive, but no other bags tested positive in Canada or the U.S., our farms and processing plant were found to be totally clear and no one was reported sick or injured. Because these two recalls involved leafy greens, I will focus on our Vegetables business. Our Vegetables business is a provider of leafy greens, as well as other commodity vegetables to retailers and wholesalers in North America. The main products on a tonnage basis that make up the leafy greens category are spring mix, spinach, romaine lettuce, iceberg lettuce and cabbage. Our Vegetables business supplies these items both in a commodity form and in a prepackaged form.

Our Vegetables business on average ships over 5,000,000 servings each and every day of nutritious products in a prepackaged form. This number of servings almost doubles when you add in our commodity produce.

When it comes to food safety, one illness is one too many. All of us at our company and in this industry have families that consume these products, and we understand first hand our responsibility to deliver products that are as safe and nutritious as possible.

TWO RECALLS

The Subcommittee staff requested that I address the two vegetable E. coli recall events that touched our Company during the last two years. First was the industry-wide halt of all spinach sales that occurred in September of 2006. On September 15, 2006, Natural Selection Foods LLC recalled all packaged fresh spinach that Natural Selection Foods produced and packaged with Best-If-Used-By dates from August 17 through October 1, 2006, because of reports of illness due to E. coli O157:H7 following consumption of packaged fresh spinach produced by Natural Selection Foods. These packages were sold under 28 different brand names, only one of which was owned by Dole. At that time, Natural Selection Foods was our sole supplier of spinach items, under a contract we had with them. On September 15, 2006, Dole announced that it supported the voluntary recall issued by Natural Selection Foods. Dole has no ownership or other economic interest in Natural Selection Foods. The U.S. Food and Drug Administration announced on September 29, 2006 that all spinach implicated in the outbreak had been traced back to Natural Selection Foods. The FDA stated that this determination was based on epidemiological and laboratory evidence obtained by multiple states and coordinated by the Centers for Disease Control and Prevention.

From what the federal and California state regulators reported after the incident, it appears that there was no problem at Natural Selection Foods' processing plant; instead the source of the problem was in one spinach farm field, owned by a reputable grower, that was being farmed organically. I understand that the Subcommittee received the testimony given last April by Charles Sweat, who is the President of Natural Selection Foods, so I will assume the Subcommittee needs no further detail on the Natural Selection recall from September 2006. At that time, we did not internally farm or package spinach. We did not have the necessary specialized machinery to produce spinach salad products and therefore had contracted with Natural Selection Foods to produce and package these products for us. Since that time, we have invested in the machinery to package spinach and other tender leaf products ourselves.

The spinach recall galvanized an industry that already approached food safety as a top priority into becoming an industry with a heightened sense of urgency of the need to understand what steps we need to take to reduce this risk even further in the future. Some of this effort has involved strengthened good agricultural practices and some has involved more testing of produce in the field, at the processing plant door and of finished product. We recognize that we are an industry that still needs to do more, and we strongly believe that government has an important role to play, particularly in supporting needed scientific research on the causes of outbreaks and in developing nationwide food safety regulation, which I will discuss further in a moment.

The other incident I wanted to talk about involved a recall of some of our salad product in Canada in September of 2007. On September 14, 2007, the Canadian Health Ministry told us that they had randomly pulled a number of bags of our salad from a store shelf in Canada, and that one had tested positive for E. coli. We immediately announced a recall of the affected lot code. We expanded the Canadian recall to parts of the United States since some of the same raw materials were used in product sold in those parts of the U.S. and Canada. None of the other Canadian bags, nor any other bags of the same production batch that we still had, nor any of the bags turned in by consumers, tested positive for E. coli or any other pathogen. Our processing plant and the farms on which the produce was grown were carefully inspected by regulators—and there was nothing there, either. More significantly, there were no illnesses reported that were associated with the product in Canada or the United States.

MOVING FORWARD—EFFORTS UNDERTAKEN AND NEEDED RESEARCH AND REGULATION

The fact our industry has had recalls should not be viewed as an indication of complacency. Research is the key to understanding the following scientific questions that need to be answered: where does this E.coli O157:H7 microorganism survive

in the natural environment, other than inside cattle, which is the primary host organism; how does E.coli O157:H7 survive in the natural environment; how is E.coli O157:H7 transferred from one location to another; and how do we kill or otherwise eradicate it, without destroying a highly perishable product? From a government support viewpoint, we believe there is severe under-funding in the area of applied research and science-based mitigation strategies. At times we are forced as an industry to react to anecdotal, or bench-top tests which cannot be replicated in real world field conditions.

You may ask: why is this so difficult a scientific problem to solve? The answer lies in how extremely rare it is to find the virulent E.coli O157:H7 on crops. For example, since the September 2006 spinach event, we instituted raw crop testing in the fields before harvesting, as well as testing of raw crops as they enter our processing plants and testing of finished product. Since September 2006, we have run approximately 4,000 of these tests to date, using state-of-the-art tests, and we have not yet had a single positive test for E.coli O157:H7.

We strongly feel that research is where the lion's share of any extra resources allocated by Congress should go. Please note that we don't have any objection to spending more federal dollars on inspections and audits. Adding more inspectors to regulatory agencies or giving them mandatory recall authority is a good thing. However, having more inspectors will not get to the root cause of how pathogens like E.coli O157:H7 survive and transfer from one location to another, and it will not address the science needed to develop a true kill step or other prevention. It's the old question of where you can get the most bang for the buck. We'd recommend that Congress put most of that extra money into well thought-out research. This Subcommittee can play an invaluable role in taking testimony from public/private panels of the best scientific minds to figure out what specific research should be funded, and in what priority order. We at Dole would be happy to share our best thoughts on this topic, too.

I want to highlight for the Subcommittee some of the additional steps that have been taken since September of 2006, in both our company, and in the industry as a whole. The leafy greens industry in California has adopted the Leafy Greens Marketing Agreement (for purposes of this hearing this is referred to as the CA–LGMA). The CA–LGMA is an unprecedented commitment to food safety. Although it is in theory voluntary, the backbone of the program is California state inspectors in the fields of CA–LGMA signatories, auditing against a set of food safety metrics established by some of the sharpest scientific minds from industry, academia, and the public sector. For example, some of the specific areas the California state inspectors audit against include irrigation water tests, employee hygiene, harvesting equipment sanitation, buffer zones, soil amendments, wildlife intrusion, and previous land use. We take pride that, not only was our Vegetables business one of the companies instrumental in driving this state-wide initiative, but our Division President is currently the Vice-Chairman of the CA–LGMA Board. Arizona has a similar LGMA program under development which is almost identical to the California program. Our Vegetables' division President also sits on the Arizona governing board, which is tasked with developing and implementing a complete audit program.

Some would criticize this program as voluntary, but please understand that the only thing voluntary about it is whether to join or not. Once you're in, compliance and government inspection are mandatory. Ninety nine percent (99%) of the leafy greens handlers in California have signed onto the program—and some got encouraged into "volunteering" by big customers who would not buy their products unless they "volunteered." So compliance and inspection are, for all intents and purposes, mandatory for the whole industry in California. The CA–LGMA program, including state inspectors, is funded by assessments paid by signatory members.

Some would argue that federal or state regulations would have been the proper avenue, instead of the CA–LGMA program. If time had not been of the essence, that route might well have made sense. The industry felt, however, that it couldn't wait for government to act. As a testament to our industry commitment to food safety, private industry developed this field audit program, from absolutely nothing to having California state inspectors in our fields performing audits, in less than four months.

The fact that our industry did not have the luxury of waiting for government to act does not mean that we think the job is finished or that there is no role for government now. On the contrary, Dole supports national food safety standards for leafy greens, and the California and Arizona programs should be the starting point toward designing and implementing these standards. In the past, leafy greens food safety was considered a West Coast problem. However, as fuel costs continue to escalate, more Midwest and East Coast states, and Canada, are learning how to grow leafy greens in climates outside of California and Arizona.

I also would like to bring to your attention another important industry initiative—the Center for Produce Safety, headquartered at the University of California, Davis. Trade groups, private companies, the University of California, and the California Department of Food and Agriculture, have funded the launch of this Center through grants. This Center is intended to be the clearing house for available produce food safety research, and to fund new scientific studies focused on strategies to mitigate risks. As discussed above, we very strongly believe that the federal government should play a key role in the research efforts.

As a company, Dole Fresh Vegetables has under taken some key initiatives aimed at providing a higher level of food safety. First is our implementation of a trace back system that is RFid driven. RFiD stands for Radio-Frequency-Identification. The process involves placing a unique tag on every bin of lettuce harvested in the field. Once a bin is filled, the tag is scanned using the global positioning system and attached so that there is a tracking record of where in the field a product originated and where it traveled after harvest. RFiD tracking is not a fire wall for food safety. It does, however, provide real time field locations to within approximately 100 feet of where the product was harvested in the event trace back is needed. The inability to quickly trace back to a specific field location hampers the ability to determine the root cause of a problem and has been a major impediment to regulatory investigators, not because our industry is unwilling, but because the technology available until now was not adequate.

Although Dole has made significant investments in developing and applying the RFiD technology to leafy greens, we have made this program available to anyone in the industry who wishes to use it, without any payment whatsoever to Dole. We believe that the members of our industry should compete with each other on quality and service, not on food safety.

As I mentioned a few moments ago, a second initiative we implemented is testing for pathogens in the field prior to harvest. Similar to the HACCP (Hazard Analysis of Critical Control Points) principles developed for NASA, we believe that testing needs to be a part of an overall risk reduction strategy and that prevention before the product leaves the field is a critical and proactive step. We are also testing produce as it enters our processing plants and as it leaves as finished product. To date we have completed approximately 4,000 of these tests for pathogens. As noted, thus far we have not had any positive test results for pathogens—at times it seems like we are looking for the proverbial "needle in a haystack." With research help from government, a lot more testing should be done, by many more companies, and when the pathogens are found in this broader effort, science will have the data on the basis of which we can eradicate this problem.

Other Dole Fresh Vegetables risk reduction activities include a full time staff of quality assurance and food safety specialists. Their primary function as it relates to food safety is to develop and implement science-based risk reduction strategies, as well as seek out and evaluate best practices within our industry as well as other food industries.

All of Dole's fields in California are irrigated by water from deep wells or city water. We test the wells once a month during the growing season, when the water is used. We will not grow, harvest or purchase crops from fields that gets flooded with runoff from other fields, let alone from cattle pastures, nor from fields that are too close to a place where cattle have been.

In addition, we contract with third-party food safety companies to supplement our auditing process, in addition to the state inspectors that are part of the California leafy greens agreement. One third-party company provides us with independent oversight to our field operations, and another is used to provide independent oversight to our salad processing plants. All of our salad processing plants have full time quality assurance staffs on site anytime the plant is operating. All of our plants operate under a defined HACCP plan, and our fields operate under a defined, formal GAP (Good Agricultural Practices) plan, as well as the CA–LGMA audit program.

We are also working with outside vendors in developing even more reliable pathogen testing kits. Because of the amount of naturally occurring beneficial bacteria that is found on all produce, rapid test kits to detect pathogens that were developed in other industries, such as the meat or poultry industries, tend to give a high rate of false positives on lettuce.

CONCLUSION

The produce industry needs to continue to move forward with refining agricultural practices as science and technology advance. We need government support for more research activities in understanding how pathogens survive and migrate in the natural environment. We also need research in developing microbial kill steps that will

work on a perishable product. The amount of research needed is significant in both time and dollars. The first agenda item for any research program is to determine the right questions to ask. We believe that the federal agency best suited to address the important issues related to leafy greens is the USDA. The USDA already has a research station set up in Salinas, California, which is in the heart of the industry, and has extensive experience with various leafy greens products. USDA also has conducted some limited applied research on pathogens, but they have been limited in scope by funding.

A group of over seventy technical experts from academia, government regulatory and research, and the private sector, met in Washington, D.C., at a research symposium co-sponsored by Dole, this past September, focusing on understanding how pathogens survive and migrate in the natural environment. Everyone present agreed that there is a daunting task ahead of us, and we just do not yet have enough science-based answers to some very practical questions. But we have to start somewhere, and we have to remain committed to the research.

We respectfully ask this Subcommittee, and, more generally, the Energy and Commerce Committee, to do whatever it can within its power to influence significant funding of pathogen research for produce. Private companies such as Dole will continue to accelerate and champion, as fast as possible, new practices and technologies aimed at eliminating food safety risks. Produce is a living, breathing tissue that does not hold up to most conventional food safety practices that work in other industries. We cannot inspect our way out of food safety problems any more than we can test our way out of it. It will continue to take a concerted and significant effort in time and funding and regulation from both the government and private sector, to make our food system—already the safest in the world—even safer. We heartily agree with this Subcommittee that we—all of us—can, in good conscience, do no less.

Mr.STUPAK. Thank you. Mr. Eisenberg, please.

STATEMENT OF DAVID A. EISENBERG, CHAIRMAN, ANRESCO LABORATORIES

Mr.EISENBERG. Thank you for inviting my testimony.

My name is David Eisenberg. I am chairman of ANRESCO Laboratories, founded in 1943. I have been with the company 34 years.

While ANRESCO was a USDA accredited meat laboratory for 30 years, from 1976 to 2006, we surrendered our accreditations this past year because we were rarely analyzing regulatory samples, and most of all because the USDA dramatically increased the cost for accreditation.

The regulatory work we perform today relates to FDA regulated imports, and it is to this role I speak today. ANRESCO has performed sampling and analytical work for importers to meet FDA requirements since 1981. Such work represents 40 percent of our business. We run almost every analysis the FDA runs routinely. Private laboratories in total employ possibly 50 people nationwide to service this very small specialized market. ANRESCO's sampling and analytical work is equivalent to that performed by the FDA's own laboratories. The FDA regulates the food in regulated imports by reviewing import entries, releasing imports it considers low risk, and sampling and analyzing at its own laboratories, imports it believes may be unsafe or otherwise violate U.S. food standards. This work is performed under its Surveillance Program.

When the FDA finds an imported product violates its standards it may place the product on Detention Without Physical Examination, DWPE, where the FDA considers the products violative until the importer proves it meets FDA standards. The importer does so by retaining a private laboratory such as ANRESCO to sample and analyze the product and to submit such results to the FDA. Only

a very small proportion of FDA regulated imports are subject to DWPE.

With this as background I am pleased to offer suggestions to improve the FDA's regulation of imports. Relating to its Surveillance Program the FDA should provide an organized forum where industry can provide advice into what imports the FDA selects for sampling. The import industry could have possibly advised the FDA that melamine was being added to wheat gluten meal in China. The FDA should reallocate its import staff so enforcement of its regulations is uniform among its 15 districts. For years the FDA has been understaffed in New York and in Los Angeles and overstaffed at smaller ports. This leads to port shopping. The FDA should allow importers to use private laboratories that it accredits to sample and analyze samples under its surveillance program. This could significantly increase the number of shipments analyzed. The FDA should eliminate its current line by line review of private laboratory submissions that waste extensive FDA staff time. The FDA must have the legal authority to audit the accredited laboratories whenever it wants to and for whatever reason it believes necessary. The incentive for importers to use private laboratories for surveillance sampling and analysis is that such laboratories will perform the work more quickly than the FDA does itself. Shipments can then be released into commerce more quickly, critical to importers. Private laboratories would be willing to pay a fee to FDA for FDA accreditation as this will provide them additional work. ISO 17025 accreditation is not an adequate basis for assuring private laboratories are competent to perform work to FDA standards. The FDA must itself accredit private laboratories and only then will it have confidence in their work and then rely on it.

Relating to the DWPE Program, while this program is excellent in concept and works well in practice for most imports, it is greatly weakened by inadequate FDA implementation. The FDA's Southwest Import District in Dallas has procedures that assure the honesty of the DWPE Program. These procedures should be adopted nationwide immediately. They include a requirement that DWPE shipments are sampled by the private laboratory. The New York district still allows importers to take their own samples. This is akin to the wolf guarding the sheep. The importer must advise the FDA in advance what private laboratory they intend to use for a given import. In the other districts when ANRESCO finds a violative import the importer usually advises us not to submit the result to the FDA. The importer may then find another private laboratory to take new samples to reanalyze the product to get the shipment released.

In June of 2006 Dr. Robert Brackett, then director of FDA's CFSAN, at the Institute of Food Technologists meeting at Orlando, Florida advised the FDA did not consider pesticide residues in foods a serious matter and it would no longer monitor them. This sent a message to the produce industry that it was not important to comply with EPA, FDA regulations. If the FDA considers its regulations governing pesticide residues in foods unnecessary it should request Congress to change the law, not ignore its responsibility to enforce it.

Twice during 2005 I met with senior FDA staff to complain the FDA was not enforcing its pesticide residue requirements on snow peas imported from Guatemala. I presented data for 25 samples ANRESCO had taken at retail and had analyzed finding 13 violative. I pleaded for FDA to take more surveillance samples. Instead the FDA reduced the number of surveillance samples it took. I was flabbergasted when I saw President George Bush on television talking from a Guatemalan farm last year praising that industry for developing an export business for produce when his appointees knew a high percentage of the product violated FDA standards, and they had facilitated its importation.

Other suggestions, the FDA should allow the electronic submission of all private laboratory reports relating to food imports, especially perishables. It is critical that the import process be as quick as possible to assure compliance with it. The FDA should not allow importers to place their products in commerce before having a release, as has been the case in south Florida. Thank you.

[The prepared statement of Mr. Eisenberg follows:]

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ANALYSIS • RESEARCH • CONSULTING

26 February 2008

Testimony of David A. Eisenberg, Chairman, Anresco, Inc. (1943) commercial analytical laboratory before the House Energy & Commerce Committee 26 February 2008.

Thank you for inviting my testimony. My name is David Eisenberg I have an MBA in Finance from the Wharton School of the University of Pennsylvania. I am Chairman and CEO of Anresco, Inc., a commercial analytical laboratory founded by my father Dr. Sylvan Eisenberg in 1943. I have been with the company for 34 years.

Anresco has performed sampling and analytical work for importers to meet FDA requirements since 1981. Such work represents approximately 40% of our total business. We employ 30 people. We are one of 3 or 4 private laboratories that together perform possibly 80% of the sampling and analyses required by importers to meet FDA requirements nationally. The range of analyses we perform is very broad, including testing for filth (microscopy), pesticide residues, drug residues, heavy metals, illegal colors and sweeteners, decomposition and microbiological contamination. Private laboratories in total employ possibly 50 people to service this very small but highly specialized market.

Anresco's sampling and analytical work is equivalent to that performed by the FDA's of

Anresco Laboratories (www.anresco.com)
1370 Van Dyke Ave.
San Francisco, CA 94124

Tel: 415 822 1100
Fax: 415 822 6615

own laboratories and our work meets FDA's "fit for use" documentary requirements. Our cost performing this work is lower than the FDA's and we generally report results more quickly. For ten years- from 1996 to 2006- I was Chairman of the San Francisco Bay Area Section of the FDA-PICSC Committee (Pacific Import Community Steering Committee). This group was organized as a result of former Vice President Gore's Initiative on Re-Inventing Government. The group consisted of Sections based in Los Angeles, San Francisco and Seattle each consisting of members from the import community- importers, customs brokers, cold storage operators, ports, private laboratories and FDA staff. The purpose of the PICSC was to provide a conduit for information from the FDA to the regulated import community and from that community back to the FDA- in the public interest to assure and improve the FDA's regulation of imports. The 3 Sections would meet 3 times each year by televideo conference. The FDA ended its involvement/sponsorship of the PICSC in early 2006.

The FDA regulates food and related imports by reviewing import entries, releasing imports it considers low risk and sampling and analyzing at its own laboratories a percentage of imports it believes may be unsafe or otherwise violate US food standards. This work is performed under its "Surveillance" Program.

The FDA sets "Defect Action Levels" for filth, methyl mercury, pesticide residues and other contaminants. These are the criteria the FDA generally uses to release or reject given imports. Many "Defect Action Levels" are available to the public. Some are not.
The percentage of import shipments the FDA samples and analyzes pursuant to its Surveillance Program has dropped from 8% in 1992 to 1.3% in 2007. This reduction has occurred because

Anresco Laboratories (www.anresco.com)
1370 Van Dyke Ave.
San Francisco, CA 94124

Tel: 415 822 1100
Fax: 415 822 6615

the volume of FDA regulated imports has grown and FDA import staff has been constant or reduced.

When the FDA finds an imported product violates its standards, it will deny entry of the shipment into commerce and will require that the importer either re-export the product, destroy it or recondition it (correct the defect). It may- at its discretion then place the product on Detention Without Physical Examination (DWPE) where the FDA considers the product violative until the importer proves it meets FDA standards. The importer does so by retaining a private laboratory such as Anresco to sample and analyze the product and to submit such results to the FDA.

Only a very small proportion of FDA regulated imports are subject to DWPE- possibly 1%.

Private laboratories may also sample and analyze shipments the FDA has found violative under its Surveillance Program as when a shipment can be segmented by lot number, size or other criteria. This does not occur very often.

With this as background, I am pleased to offer comments and suggestions to improve the efficacy of FDA's regulation of imports.

Relating to the FDA's Surveillance Program

1. The FDA should provide an organized forum either via the PICSC or other venue where industry can provide advice/input into what imports the FDA should select for sampling and for what "Defect Action Levels" are appropriate. The FDA should review these on

Anresco Laboratories (www.anresco.com)
1370 Van Dyke Ave.
San Francisco, CA 94124

Tel: 415 822 1100
Fax: 415 822 6615

an ongoing basis. The import industry can provide the FDA important and useful advice (i.e., that melamine was being added to wheat gluten meal in China).

2. The FDA should re-allocate its import staff so enforcement of its regulations is uniform among its 15 Districts. For years, the FDA has been understaffed in New York and in Los Angeles and overstaffed at smaller ports. At least until 1998, the likelihood of FDA stopping an import was 3 to 5 times greater in the San Francisco District than in the Los Angeles District. This caused importers to "port shop" making the inequities even greater as freight diverted to understaffed ports.
3. The FDA should again- as it did until about 2003, post at its website information on all Import Detentions- whether the detention was from its Surveillance Program or the DWPE Program. This allowed the import industry to know if FDA enforcement was consistent between its Districts. The suspicion of unequal enforcement is enough to cause "port shopping".
4. The FDA should allow importers to use "approved" private laboratories to sample and analyze samples under its "Surveillance Program". This would expedite the release of shipments and allow the FDA to significantly increase the number of shipments sampled and analyzed. The FDA should assume private laboratory submissions meet its requirements if the FDA has approved that laboratory in advance of the shipment. The FDA should then eliminate its current line by line review of private laboratory submissions that wastes a great deal of FDA staff time and delays shipments.

Anresco Laboratories (www.anresco.com)
1370 Van Dyke Ave.
San Francisco, CA 94124

Tel: 415 822 1100
Fax: 415 822 6615

5. The FDA must have the legal authority to assure itself private laboratories provide FDA equivalent sampling and analytical work. The FDA itself must Certify, Accredit or otherwise approve private laboratories. The FDA must: a) have the right to physically visit/audit private laboratories at any time- to assure itself of the adequacy of the laboratory facilities, instrumentation and staff, b) run a "check sample" program where samples it prepares with known contaminants are sent to and analyzed by the private laboratories with results reported back to the FDA- as a means of verifying the competence of the laboratories, c) approve the financial responsibility and the integrity/honesty of laboratory management and d) provide approved laboratories ready access to its technical and compliance requirements and "due process" when the FDA finds deficiencies in private laboratory work. The FDA should disqualify a private laboratory only as a last resort.
6. The incentive for importers to use private laboratories and pay for such use for Surveillance sampling and analysis is that such laboratories will perform the work more quickly than the FDA's own laboratory and the shipment can be released into commerce more quickly.
7. Private laboratories would be willing to pay a fee for FDA Certification, Accreditation or approval as this will provide them additional work.
8. ISO 17025 Accreditation is NOT an adequate basis for assuring private laboratories are technically and administratively competent to perform work meeting FDA's standards. Private laboratories such as Anresco perform a broad variety of highly specialized

Anresco Laboratories (www.anresco.com)
1370 Van Dyke Ave.
San Francisco, CA 94124

Tel: 415 822 1100
Fax: 415 822 6615

analyses for submission to FDA. FDA's requirements are generally for "legal quality" work and it requires a team skilled in FDA's technical and administrative requirements to fairly evaluate the private laboratory. Only the FDA has the resources to do this.

9. By utilizing private laboratories in the FDA's Surveillance Program, the Agency could substantially increase the percentage of import shipments sampled and analyzed at no added cost to the taxpayer. The use of private laboratories could also free up FDA compliance personnel to make more cargo and warehouse inspections and its technical personnel to develop new methods for contaminants not now considered. If the FDA has more time to investigate potential problems, it will find them. In 1997, Operation "Bad Apple" found 40% of import shipments were not available at importers warehouses after FDA found them violative and 21.4% of import shipment documentation did not correctly identify of cargo.

Relating to the FDA's Detention without Physical Examination (DWPE) Program

While this Program is excellent in concept and works well in practice for most imports, it is greatly weakened by inadequate or non-caring FDA implementation.

The FDA Southwest Import District - SWID based in Dallas, Texas has in place procedures that assure the honesty of the DWPE Program. These procedures should be adopted nationwide. They include:

Anresco Laboratories (www.anresco.com)
1370 Van Dyke Ave.
San Francisco, CA 94124

Tel: 415 822 1100
Fax: 415 822 6615

1. A requirement that DWPE shipments be sampled by the private laboratory. The New York District still allows importers to take their own samples. This is akin to the wolf guarding the sheep. If independent samplers take samples and provide these to a private laboratory and the results are wrong, it is usually impossible to determine who was at fault. The laboratory must be the responsible party.
2. Analytical results must be submitted to the FDA directly by the private laboratory (this procedure now may apply generally). Some years ago, Anresco encountered two situations where importers deleted information from reports that evidenced FDA violations and then submitted the corrupted Reports to the FDA.
3. The importer must advise the FDA in advance what private laboratory they intend to use for a given import. In the other FDA Districts, this is not required. Except in SWID, when Anresco finds a violative import the importer usually advises us not to submit the result. The importer may then find another private laboratory to take new samples and to re-analyze the product to get the shipment released.

Non-Caring FDA implementation of its rules/regulations:

1. In June 2006, Dr. Robert Brackett then Director of the FDA Center for Food Safety and Applied Nutrition at the Institute of Food Technologists Meeting at Orlando, Florida advised FDA did not consider pesticide residues in foods a serious matter and it would no longer monitor them. This sent a message to fruit and vegetable growers, shippers and

Anresco Laboratories (www.anresco.com)
1370 Van Dyke Ave.
San Francisco, CA 94124

Tel: 415 822 1100
Fax: 415 822 6615

importers and to private laboratories there was no need to comply with EPA/FDA regulations. Anresco chose not to cheat and we lost our business in South Florida. If the FDA considers its regulations governing pesticide residues in foods unnecessary, then it should request Congress to change the law not ignore it.

2. Twice during 2005, I met with senior FDA staff the second time with Margaret Glavin, Associate Commissioner for Regulatory Affairs to complain the FDA was not adequately enforcing its pesticide residue requirements on snowpeas imported from Guatemala. I presented data for 25 samples Anresco had taken at retail in the greater Miami area during 2004 and had analyzed with 13 being violative of FDA standards. I pleaded for FDA to take more Surveillance Samples and to then place violative shippers on DWPE status as it had done in prior years. Even though FDA had found a high percentage of violations itself, the result of my pleading was FDA reduced by 50% the number of Surveillance samples analyzed. I was flabbergasted when I saw President George Bush on television talking from a Guatemalan farm last year praising that country for developing an export industry for produce when his appointees knew a high percentage of the product violated US food standards and they had facilitated its importation.

Two more suggestions:

1. FDA should allow electronic submission of all private laboratory Reports relating to food imports- especially perishables. Anresco has pioneered this with the FDA Southeast

Anresco Laboratories (www.anresco.com)
1370 Van Dyke Ave.
San Francisco, CA 94124

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Fax: 415 822 6615

Regional Laboratory in Atlanta and with the FDA Miami Compliance Office. With electronic review, Anresco can sample an import on a Tuesday in Miami, analyze it Wednesday at San Francisco and the FDA can release it Thursday morning.

2. With a fast turnaround of results, importers can comply with applicable FDA rules and regulations. The FDA should not allow the importers to place their products in commerce before having a release.

Thank you for considering my comments and suggestions.

David A. Eisenberg
Chairman
Anresco Inc.

Anresco Laboratories (www.anresco.com)
1370 Van Dyke Ave.
San Francisco, CA 94124

Tel: 415 822 1100
Fax: 415 822 6615

Mr.STUPAK. Thank you, Mr. Eisenberg.
Dr. Brackett, your testimony, please.

STATEMENT OF ROBERT E. BRACKETT, PHD, SENIOR VICE PRESIDENT AND CHIEF SCIENCE AND REGULATORY AFFAIRS OFFICER, GROCERY MANUFACTURERS ASSOCIATION

Dr.BRACKETT. Thank you, Mr. Chairman.
Good afternoon to the rest of the committee.
I am Robert Brackett, Senior Vice President and Chief Science and Regulatory Affairs Officer at Grocery Manufacturers Association.
Food companies recognize our responsibility to ensure that the food we provide to consumers is safe. To address the challenges posed by rising imports and changing consumer preferences we constantly identify under duress potential sources of contamination throughout each product's life cycle. We have made significant new investments in food safety, identifying and adapting a range of practices in programs to reduce the risk of contamination. Food safety is our top priority.
Ultimately, the burden of providing safe food falls on our industry, but this responsibility is shared by federal, state and local agencies. By setting and enforcing tough food safety standards agencies like FDA and USDA's food safety inspection service help the food industry to ensure that the safety of our food supply is as safe as it can be.
Providing these agencies with adequate resources is critical to their ability to help the food industry ensure the safety of our food. As director of FDA's Center for Food Safety and Applied Nutrition between 2004 and 2007 I routinely stated to the agency the critical need for more resources. In my view, FDA's food safety and food related programs were willfully inadequate and I shared that view with the agency. But despite my best efforts funding for FDA food related programs barely kept pace with inflation. As a result more than 800 scientists, inspectors, and other critical staff have been lost in the last four years, including some of FDA's most experienced experts. Recent nationwide recalls remind us how devastating food borne illness can be and how critical it is for FDA to respond quickly to safety problems. It is important to maintain this level of response, but there is a need—but there needs to be an increased focus on prevention and intervention to stop these outbreaks from happening in the first place. The adoption of preventative controls to prevent contamination, the use of modern testing strategies to detect pathogens before the product is released and application of innovative new processing technologies to destroy pathogens all have a role in improving the safety of our foods.
While at CFSAN we recommended a variety of options to address the safety of foods, including the proposal to improve produce safety that could include a requirement for tough, but enforceable produce safety standards. A position that is not only shared by, but has actually been requested by, the food industry and many farm organizations. The overall goals of the plan were to prevent contamination, minimize public health impact in the event that contaminated product did get into the marketplace, to enhance the capability to provide safe products, and also to improve communica-

tions to both domestic as well as foreign suppliers. And also facilitating and supporting the science that should always be the underpinning of any food safety effort.

Interestingly, these recommendations contained elements that specifically addressed actions that were recommended later in the same year in GMA's four pillars document, as well as FDA's Food Protection Plan. Unfortunately, the Administration did not seek funds for the plan and Congress failed to provide adequate funding as well. Consequently, the industry decided to act on its own through promoting their and statewide regulations and marketing orders.

In addition to requiring tough, but enforceable produce standards, Congress should also require FDA to complete their proposed modernization of good manufacturing practice standards, or GMPs, and require food importers to document the food safety efforts of their foreign suppliers. In the highly unlikely situation that a company refused to voluntarily recall a product that poses a severe health consequence, FDA should be given the power to order a recall. FDA could also do much more to rebuild FDA's scientific and information technology capacity, and could do more to build capacity of foreign governments to ensure the safety of our imported foods.

The food industry supports giving FDA new responsibilities that would help ensure the safety of our food, but new responsibilities without new resources will not improve the safety of our food supplies. In fact, new responsibilities without requisite resources to carry out those responsibilities has just the opposite affect. It dilutes out existing efforts in safety and makes FDA less able to address the real food safety issues. Likewise, new restrictions on ports of entry, new penalties or any new labeling requirements will also not result in a safer food supply for the American people. By focusing our efforts on prevention, by increasing FDA resources and by leveraging the expertise in resources of the food industry itself Congress can help us meet the challenges posed by rising imports and changing consumer preferences.

Thank you. I will be happy to answer any questions.

[The prepared statement of Mr. Brackett follows:]

Summary of Brackett Testimony

Steadily increasing food imports and changing consumer preferences pose new challenges for food and beverage companies and for the Food and Drug Administration. To address these challenges, food companies and federal and state agencies have placed continually greater emphasis on the prevention of food contamination.

As Congress considers food safety legislation, we urge you to consider the following recommendations:

One, we urge you to require that every food importer of record institute a foreign supplier quality assurance program that assures that all imported ingredients and products meet FDA food safety and quality requirements.

Two, we urge you to expand FDA's ability to build the capacity of foreign governments to prevent and detect threats to food safety. In particular, FDA should be directed to work with foreign governments to expand training, accelerate the development of laboratories, ensure the compliance of exports with U.S. regulations, and harmonize food safety requirements among countries.

Three, we urge you to enhance FDA's ability to target those imports that pose the greatest risk to consumers. In particular, we urge you to create a voluntary program to permit expedited entry of foods that pose no meaningful risk. By permitting food importers who demonstrate the existence of a secure supply chain and who meet FDA's standards and conditions to receive expedited entry, FDA could focus more scrutiny on those imports that are more likely to pose a risk to public health.

Four, we urge you to provide FDA authority to mandate that fruits and vegetables be produced following good agricultural practices. Rising consumption of fruits and vegetables creates new food safety challenges that should be addressed through strong and enforceable produce safety standards which can be tailored to reflect differences among commodities.

Five, we urge you to give FDA the authority to order a mandatory recall when a company has refused to conduct a voluntary recall and there is a significant risk to public health. Where the responsible party refuses to voluntarily recall a product for which there is a reasonable probability that the food will cause serious adverse health consequences or death, the Secretary should be permitted to order the company to conduct a recall.

Finally, we urge you to work with your colleagues on the appropriations committee to provide FDA with adequate resources. Because FDA food-related funding has not kept pace with inflation, more than 800 scientists, inspectors and other critical staff have been lost during the past four years. We urge you to reject taxes on food imports and facilities and to instead work with the Alliance for a Stronger FDA to increase FDA food-related spending by $150 million in FY 2009.

Written Testimony of Dr. Robert Brackett

Grocery Manufacturers Association

Senior Vice President and Chief Science and Regulatory Affairs Officer
Grocery Manufacturers Association

Before

Committee on Energy and Commerce
Oversight and Investigations Subcommittee
United States House of Representatives

"Contaminated Food: Private Sector Accountability"

February 26, 2008

Good morning. I am Robert Brackett, Senior Vice President and Chief Science and Regulatory Affairs Officer for the Grocery Manufacturers Association.

Americans enjoy one of the safest food supplies in the world, but food and beverage companies recognize that steps must be taken to make our food supply even safer. Ensuring the safety of our products -- and thereby maintaining the confidence of consumers -- is the single most important goal of the food and beverage industry. Product safety is the foundation of consumer trust, and our industry devotes enormous resources to ensure that our products are safe.

Steadily increasing food imports and changing consumer preferences pose new challenges for food and beverage companies and for the Food and Drug Administration. In recent years, we have experienced dramatic changes in the volume and variety of food imports. The percent of food imported into the U.S. increased by nearly 40 percent

between 1995 and 2005 to 15 percent of the U.S. food supply. In particular, roughly 60 percent of the fruits and vegetables and roughly 80 percent of seafood now consumed in the U.S. are imported.

To address the challenges posed by rising imports and changing consumer choices, food and beverage companies and federal and state agencies have placed continually greater emphasis on the prevention of food contamination. By constantly identifying and addressing the sources of contamination throughout each product's life cycle, we continually reduce the risk of food-borne illness to consumers. We believe that the prevention of contamination – through the adoption of preventive controls – should continue to be the foundation of our nation's food safety strategies.

Food companies recognize our responsibility to provide safe food to consumers. We have made significant new investments in food safety, identifying and adopting a range of practices and programs to reduce the risk of contamination. Earlier this month, for example, we convened a Webinar (or web-based training) on improving industry controls for processing of low acid canned foods. This type of activity is one of industry's actions to improve the safety of foods by providing specialized training to food processors.

Although the ultimate burden of providing safe food falls on our industry, this responsibility is shared by federal, state and local agencies. By setting and enforcing tough food safety standards, agencies like FDA and FSIS help the food industry ensure the safety of our food supply. We believe that providing federal, state and local food

safety resources with adequate resources is critical to ensuring that America continues to enjoy one of the world's safest food supplies.

As you seek to modernize food safety legislation, we urge you to focus on programs and policies that will prevent food contamination and to consider the following recommendations. Many of these recommendations were included in *Commitment to Consumers: the Four Pillars of Imported Food Safety,* a comprehensive food safety proposal released last fall by the Grocery Manufacturers Association.

One, we urge you to require that every food importer of record institute a foreign supplier quality assurance program that assures that all imported ingredients and products meet FDA food safety and quality requirements. To assist companies in developing these supplier quality programs, we propose that FDA issue guidance on key elements—including, as appropriate, audits, testing, good manufacturing practices, food defense programs, good agricultural practices, and other preventive controls. Requiring food importers to ensure the safety of their supply chains – and giving FDA the authority to oversee industry's implementation of these programs – would significantly reduce the likelihood of contamination.

Two, we further urge you to expand FDA's ability to build the capacity of foreign governments to prevent and detect threats to food safety. In particular, FDA should be directed to work with foreign governments to expand training, accelerate the development of laboratories, ensure the compliance of exports with U.S. regulations, and harmonize food safety requirements among countries. FDA should also be given the

authority to detain food imports if inspections of foreign facilities are warranted but are unduly delayed or refused, as proposed by FDA in the agency's Food Protection Plan.

Three, we urge you to enhance FDA's ability to target those imports that pose the greatest risk to consumers. In particular, we urge you to create a voluntary program to permit expedited entry of foods that pose no meaningful risk. By permitting food importers who demonstrate the existence of a secure supply chain and who meet FDA's standards and conditions to receive expedited entry, FDA could focus more scrutiny on those imports that are more likely to pose a risk to public health. A risk-based approach to food inspections, combined with enhanced training of FDA and other federal and state inspectors, would significantly improve our ability to detect contaminated food. In addition, FDA should build upon existing efforts to ensure the safety of imported foods from countries or companies with a history of problems by working with those foreign governments and food companies to certify the safety of such products before they are offered for import into the U.S. Increasing our ability to scrutinize and oversee imports based on risk would greatly enhance our ability to detect threats to public health without crippling commerce or violating our trade commitments.

Fourth, we urge you to take steps to continually improve the safety of food produced in the U.S. In particular, we urge you to provide FDA authority to mandate that produce be produced following good agricultural practices. Rising consumption of fruits and vegetables reflects growing consumer demand for healthier food choices but also creates new food safety challenges that should be addressed through strong and enforceable produce safety standards which can be tailored to reflect differences among

commodities. Similarly, we support modernizing preventative controls for packaged food products to reflect scientific advances and thereby strengthen the foundational elements of our food safety system.

Fifth, we urge you to give FDA the authority to order a mandatory recall when a company has refused to conduct a voluntary recall and there is a significant risk to public health. Specifically, where the responsible party refuses to voluntarily recall a product for which there is a reasonable probability that the food will cause serious adverse health consequences or death, the Secretary should be permitted to order the company to conduct a recall.

Finally, we urge you to work with your colleagues on the appropriations committee to provide FDA with adequate resources. Because FDA food-related funding has not kept pace with inflation, more than 800 scientists, inspectors and other critical staff have been lost during the past four years. We urge you to reject taxes on food imports and facilities and to instead work with the Alliance for a Stronger FDA to increase FDA food-related spending by $150 million in FY 2009.

We believe the adoption of these and other recommendations identified in our *Four Pillars* proposal will, in combination, ensure that Americans continue to enjoy the one of safest food supplies in the world. By focusing our efforts on prevention, by increasing FDA resources, and by leveraging the expertise and resources of the food industry, we believe Congress can help us meet the challenges posed by rising imports and changing consumer preferences.

Mr.STUPAK. Thank you, and thank you to everyone on this panel.

We are expecting votes. We are going to get going and see how many we can through here before we have to run off for our votes.

We are going to go five minutes and we will probably go a second or third round if necessary.

Mr. Shoemaker, we got Mr. Rodkin there. I am a little confused on what happens, especially on the pot pies, because tests performed by ConAgra or Banquet showed that all the meat pies were prepared with the same equipment. Since the turkey pot pies contained salmonella where else could the bacteria have come from but the turkey? I'm sorry. Yeah, go ahead.

Mr.SHOEMAKER. I can only address what has happened within the Butterball facilities, the four walls there. I have no knowledge of ConAgra's facilities. But within our four walls we met the kill step, we met the low bacterial level and then also all tests within that facility have proven that it was negative for salmonella.

Mr.STUPAK. OK.

Mr.SHOEMAKER. Also the salmonella strain that was found was a strain that has been found in chickens in all but one incident——

Mr.STUPAK. But not in the pot pies?

Mr.SHOEMAKER. And in turkey only once, and that was not within our system.

Mr.STUPAK. Right. But there was the vote. Son of a gun. OK. Let me ask you this. You said you monitor and control temperature. Why don't you test for salmonella and other bacteria right after the product is cooked instead of waiting until it is chilled?

Mr.SHOEMAKER. Whenever you look at a cook in the bag product, a low risk product, we have specifications from all of our customers how you want to check it. What are the specifications, whether it is a size, whether it is the regime on checking the product, there was not a test to check because it being a low risk and had gone through the kill step and——

Mr.STUPAK. So if your customer would ask you to——

Mr.SHOEMAKER. In other words——

Mr.STUPAK [continuing]. Check right after the cooking, you would do it then before you chilled it?

Mr.SHOEMAKER. Yes, we would. We would do whatever our customer asked.

Mr.STUPAK. OK. Does that make sense, Mr. Rodkin, then? Let us say on turkeys to test for salmonella after it is cooked, before it is cooled?

Mr.RODKIN. I am not an expert——

Mr.STUPAK. OK.

Mr.RODKIN [continuing]. On that, but I believe that is one of the steps that we have implemented subsequently. I also will agree with Mr. Shoemaker that they cooperated fully and we never were able to say exactly, precisely that it was an issue with the Butterball turkey. So I want to agree with that, but I can also—yes?

Mr.STUPAK. Where does it come from then?

Mr.RODKIN. Yes.

Mr.STUPAK. I mean I guess that is——

Mr.RODKIN. Yes.

Mr.STUPAK. And being a consumer and not a scientist I guess I am asking the same question.

Mr.RODKIN. Sure.

Mr.STUPAK. You are telling me it is not you. You are telling me it is not you. Where does it come from?

Mr.RODKIN. Well, on the first day that we became aware of the issue we knew very little about the source, but we did know as Mr. Shoemaker has said that any possible salmonella would be killed through proper cooking, because salmonella can't survive past—beyond 165 degrees.

Mr.STUPAK. Right.

Mr.RODKIN. So consumers are not at fault. They should expect safe product. This generated an intensive analysis of our cooking directions and microwave performance. But also because it was our absolute responsibility to find the root cause in the product we took over 3,000 samples of product we had from finished pot pies and were able to isolate salmonella in just 17. Those all happened to be Banquet turkey pot pies from two dates in July of 2007. But despite very intensive investigations and analysis and cooperation we were not able to determine the exact, precise source of the contamination. It was not absolutely proven and, therefore, we had our people take the broadest possible approach and assume that all possible sources were or could be the source. And as a result we have made some extremely——

Mr.STUPAK. Well, let me ask you this. If it is not the packaging, if it is not the turkey, if it is not the machine, could it come from the gravy? Is the gravy made from a separate firm that comes into your pot pies?

Mr.RODKIN. We have checked every last ingredient and have found no source of salmonella. And, therefore, because we care very deeply about making the safest food possible. We took a number of steps across the board in that facility to make sure that all raw materials now have tighter specifications——

Mr.STUPAK. Sure. Let me put my consumer hat back on.

Mr.RODKIN. Yes.

Mr.STUPAK. So if you have tested everything and Butterball says not our fault, but yet we have salmonella, then how can Americans be sure that the next pot pie they buy won't have salmonella in it? If it is not the gravy, it is not the packaging, it is not the turkey, it is not the cooking, it is not the microwave, it is not nothing. How do we know then?

Mr.RODKIN. Again, having made all of these changes——

Mr.STUPAK. Right.

Mr.RODKIN [continuing]. That I was describing and in working in conjunction with the USDA I did mention that in the slightest possible chance that any salmonella could come through the process it would be killed with proper cooking. And, therefore, we took a very intensive look at our instructions and at microwaves.

Mr.STUPAK. Right.

Mr.RODKIN. And found much greater variability than we had historically in microwaves and, therefore—this was our old package. Sorry it is so small. I hope you can see that. But importantly on the back are where the instructions are. We have made changes before we reintroduced the product into the marketplace. Took off where it says ready in four minutes in a microwave.

Mr.STUPAK. Right.

Mr.RODKIN. Said microwaveable, but must be cooked thoroughly. See back for directions. And now the directions have been changed——

Mr.STUPAK. So the answer is to cook it longer for the consumer then, in other words?

Mr.RODKIN. That is what——

Mr.STUPAK. I guess I am trying to—my time is up and they are calling us for votes. Let me ask you one more. On the Peter Pan peanut butter for salmonella, again, ConAgra didn't find it, but the FDA did. What changes were made in Peter Pan then? I mean I think Peter Pan you have the salmonella and said it was a leaky roof. That was repaired and we still found it after that, after a new batch, so——

Mr.RODKIN. That is a question I need clarification on, because we have not found any salmonella subsequently.

Ms.DEGETTE. If the gentlemen will yield. It was the FDA that found the salmonella.

Mr.RODKIN. Right.

Ms.DEGETTE. Not you.

Mr.STUPAK. After——

Mr.RODKIN. And I need some clarification on that, because with this we are unaware of that.

Mr.STUPAK. OK.

Mr.RODKIN. We are unaware of that because we closed the facility down immediately and only reopened last August. And it is an extremely different facility, totally redone, totally remade. And, again, it is because we are extremely concerned about, as Mr. Marler said, food safety risk is a bad business decision.

Mr.STUPAK. OK. Our votes are up. We got three votes on. I think now is probably appropriate time, Mr. Dingell, unless you want to go. All right. Let us—yeah. Well, we are going to adjourn for—until 12:50, one o'clock?

Mr.DINGELL. Yeah.

Mr.STUPAK. One o'clock, two o'clock? How about 1:50? 1:50. That will give us 40 minutes and we are going to have votes. And the first one is just up that usually extends more than 15 minutes, so I think with three votes we better give it 40 minutes. We will recess until then. We will be back at 1:50. Thank you.

[Recess.]

Mr.STUPAK. The Committee will come back to order. Oh, mics are much better. Thanks.

Mr. Shimkus, for questions, please.

Mr.SHIMKUS. Thank you, Mr. Chairman.

I want to thank the panelists for being here. I had to make sure I got my own processed food while I am going back and forth to vote. It is a glamorous lifestyle we have here, and this is our lunch.

So a couple things. First of all, especially with the CEO's who are present. Can you maximize shareholder wealth by producing unsafe foods and having recalls? Yeah?

Mr.RODKIN. First, if I might. I would just like to clarify when before we left for lunch there was a question on peanut butter. And I wanted to clarify to let you know that the product that was discussed that FDA found salmonella was recalled product. That was product that they found in our plant that we had already recalled.

The plant had been shut down for six months, so this was not product out in the marketplace. It is the reason that we did the recall, and it is the reason that we had such a major renovation, total remake of our facility. We did not just fix the roof. It was a total facility. All the equipment, all the testing procedures, additional personnel. I can tell you it is many, many millions of dollars and it is now the state-of-the-art facility from a peanut butter manufacturing standpoint. So I wanted to just make sure I clarified that.

Onto your question. Taking any kind of food safety risk is a really bad business decision as Mr. Marler talked about. There is nothing worse than thinking that one of your products could cause someone harm. It does damage to your brands, consumer perception, and that is our most valuable asset on our books. It harms relations with your customers. By that I mean our retailers, because you have to remove product from their shelves. And it is a big, big financial burden I can tell you from a peanut butter standpoint, and the corrections that I just talked about and all the costs of that recall are many multiple years of the brand's profit.

Mr.SHIMKUS. And I am sure that will really kind of be a similar answer as far as, you know, name ID, a product line, safety of food, and your reliable customers. I mean it really does take a dive when things like this happen. I mean so everyone agrees with that. I mean it is not a marketing ploy to want to do this. In fact, it is damaging across the board. And I think it is also important that we understand raising a capital formation for the risks involved, the return on the investment and all those challenges that operate. Of all, we were talking about some on the walk over to the votes. I mean we do have lapses, and that is kind of what we are trying to—the folks who are on now, because we do have a safe food supply. We are consuming a multitude of pounds of food in this country by the second, and but we do have lapses.

When we talk about a recall, a voluntary recall, from the amount of the lot and the batch, whatever you all decide to finally—it is voluntary so you are going to recall a product that has been produced from one of your factories. That occurs after the fact that the product has been on the shelf. Someone has purchased it, and there has been in essence an adverse reaction. So if you take the lot, the 100 percent of the product line, from whatever window you decide the recall needs to occur, how much—what percentage actually returns? How much? What percentage actually consumed and gone? So when—if you were to receive everything back. Say you say, OK, let us do a voluntary recall of peanut butter, and it is going to be this lot of whatever. What percentage actually would come back? And in this case you were given the answer to the question of the Chairman of the reinspected of the lots that had returned. But how much? What is it, 10 percent of a product line that once you recall after it has been out in the consumer sector and some of it had been consumed, some of them purchased and probably in some—on some shelf somewhere? What is the percentage? Why don't we just go to the top four food processors here.

Mr.RODKIN. I can't give you an exact percentage. I can tell you it is significant. And, I guess, the most——

Mr.SHIMKUS. What is that, 50—what is it? I mean——

Mr.RODKIN. Well, I think the most important thing is in the case of our two recalls, we recalled total production, everything, 100 percent. And that meant destroying all of our own inventory, taking all the product, 100 percent of the product, off the retailer's shelves.

Mr.SHIMKUS. But a lot of that had been consumed and purchased in the food chain, correct?

Mr.RODKIN. It is possible that some of it could have. I mean——

Mr.SHIMKUS. I am a big peanut butter eater.

Mr.RODKIN. Yes.

Mr.SHIMKUS. All right. So we go through peanut butter pretty quick in our household. So a lot of that, if it is—my question is—and I don't want to be simplistic. But, yeah, how much product, if you are just doing a basic percentage of any type of product, how much is actually returned to you all in a recall?

Mr.RODKIN. Yeah. In the case of peanut butter it was very significant. I don't know exactly what the numbers were. I can——

Mr.SHIMKUS. As significant at 30 percent?

Mr.RODKIN. Yes.

Mr.SHIMKUS. Twenty-five percent?

Mr.RODKIN. Yes, at least that.

Mr.SHIMKUS. At least. Is that normal? Why don't we—Mr. Shoemaker?

Mr.SHOEMAKER. I think that when you are talking about this I think there is different types of premises you have got to go by. We have never had a recall at Butterball, but we do mock recalls. And within our mock recall it goes back to do you know where your product's coming from? We have the ability by daily lots on some products to break where the lots are. And on some of the products, depending on their risk level, might be test and hold. So 100 percent of that product might be in our own facility, but it just depends on your category of risk as to what our percentage of products would be that we would capture back.

Mr.SHIMKUS. Mr. Lischewski?

Mr.LISCHEWSKI. We have a—our example is a bit more specific. When we did the Castleberry's recall we recalled over two years worth of product until we isolated the problem. When we isolated it down to two product codes, to this date we have been able to pull back approximately 74 percent of the product under our control. Now, on top of that we allowed retailers, rather than return it to us, to destroy product at their location. And consumers were allowed to destroy product at home and just send in for a refund regardless of whether it was one of the actual product codes involved, or any of our other products. So 74 percent of ours are able to track absolutely. The other 26 percent, again, we are not sure how much of that would have been destroyed by retailers, consumers, or it would have been consumed.

Mr.SHIMKUS. Mr. Ray?

Mr.RAY. Congressmen, our situation, our recalls required our—recommended that consumers destroy the product and not return it. And so we had a very low percentage of product returned.

Mr.SHIMKUS. How do we know that the consumers comply? I mean the reality is you have—the postal service clerks can—

canned foods for food shelters and stuff. How—we just don't know do we?

Mr.RAY. No.

Mr.SHIMKUS. I mean we all hope that they do. We are hoping that they, first of all, know about it. Even though our best efforts, we don't—our best effort is to educate the consumers that they have trouble. But then we don't, we really don't know where, especially when you are asking the consumer to destroy it.

Mr.RAY. In our particular situation most of our products that have been affected have been food service products, so we have been able to go to the distributor. The distributor then can go to their consumer. And I think it can get good withdrawal in that scenario.

Mr.SHIMKUS. Let me finish. And Mr. DeLorenzo, I'm sorry. I didn't want to leave you out there. Yeah, the camera is blocking mine.

Mr.DELORENZO. Yes. On the—we have perishable products for the most part that we are talking about here, and so we even have a—percent actually returned, but——

Mr.SHIMKUS. Can you check and see if there should a button or two?

Mr.DELORENZO. There is a green light. I thought it was on. So the bags that were actually returned are few. How much is destroyed as we say? I will say though, Congressmen, that from what I could see from this last recall there was very, very good coverage in the media. The radio—I think it must be by law that every radio station, every television station. So I think at least from that perspective there was very, very good coverage. But in terms of what is actually returned it is a small amount.

Mr.SHIMKUS. The—and finally, all these cases are different. They have, you know, different criteria. It is great for the panel to understand the enormity of the problem, but it is very difficult to, you know, get into each little—I am not going to get into each little manufacturing problem or stuff, so I would like to end this. Obviously there we have had problems, and we would like to get to zero defects. We know we don't live in a perfect world, but everybody wants this, and it is good for you, it is good for your shareholders, it is good for the safety of our constituents. How many of these—and I also, from a military background having watched the Army IG and inspector general come down and say I am from, you know, the IG. I am here to help you. Usually that is not always a good sign. And though I think they are intended to be helpful, sometimes we feel them as not being as helpful as they can be. So what, in your estimation, is the aspect of some of these problems either in good manufacturing practices or the lack thereof? Lack of federal regulations or legislation, or nominally that we are talking about with these changes in pathogens that is unidentifiable? I mean a lot of these things there is a valve that didn't close or didn't open. We have other issues. What do we need to do to be—we would like to be from the Federal Government. We would like to be helpful. We would like not to be harmful. So give us your things on how we can be helpful, and go with Mr. Rodkin.

Mr.RODKIN. One thing I would say is that while I don't really want to speak for the regulatory bodies, FDA, USDA or CDC, I

would tell you that if we could have, we as the manufacturers, could have access to the information earlier in the process, rather than right at the very end it would help us to protect consumer health. It would allow us to take any kind of necessary actions sooner, rather than having it dumped all at once and then have to spring into action. So we would like to be brought into the process much sooner.

Mr.SHIMKUS. I think that is a great response. Thank you. Mr. Shoemaker, anything?

Mr.SHOEMAKER. I think it goes back to your HACCP Program and your processes and procedures, and how strict you have your HACCP Program. The industry writes their HACCP Program. I have had a lot of people come into our facilities and say, you do not manufacture product for productivity the way you manufacture product and overcooked product and do things for lethality of bacteria. That is what you work for, and that is what we do focus on. It is for food safety. And it depends on the degrees within your HACCP Program as to how tight you want to do it. You can overdo and you can do at a marginal level. Our philosophy is to overdo.

Mr.SHIMKUS. Mr. Lischewski?

Mr.LISCHEWSKI. I think one of the areas where we see an opportunity is really more consistency. You know, if you look at our Augusta factory, we run both USDA and FDA products and so in some cases we are under two different types of criteria in terms of the product that we are producing.

Mr.SHIMKUS. Mr. Ray?

Mr.RAY. I would say a very important issue for us is research, continued research in food safety. In our particular situation as we are dealing with an issue that we have not gotten to the conclusion at this point in time, some of the research that we are looking at goes back into the early 1980's. And to be able, as an industry, to fund research to learn more about food safety of canned and canned low acid vegetables would be very important to us.

Mr.SHIMKUS. And, Mr. DeLorenzo?

Mr.DELORENZO. I think that there has to be a clear regulation and very definitive regulation as to procedures of processes and testing that entire industries have to follow. And there has to be complete transparency, and it should work on both sides on part of the FDA, USDA and the industry so that any and all records are immediately available. There is no such thing as Mr. Eisenberg testified earlier that someone could take a test and then hide it somehow. So this transparency is very important and I think clear and definitive guidelines are important. I think on the one big issue that concerns me the most is this E. coli problem, and their research is definitely necessary.

Mr.SHIMKUS. Thank you. And I am going to end with that, but I was just going to follow up with a statement. That I found interesting about both panels is the fact that this really goes back to real time information. If we are talking about the health and safety of the public food source then I don't care who has information. That information needs to go to folks that can take action on that. There shouldn't be a delay, you know, whether it is law enforcement or whether it is proprietary information based upon the people that you are contracted to do testing for. We have got to have

a way to have the information. The sooner the information, the better.

So thank you, Mr. Chairman, you have been very generous with the time. I yield back.

Mr.STUPAK. Thank you, Mr. Shimkus.

Mr. Dingell, for questions, please.

Mr.DINGELL. Mr. Chairman, thank you.

Mr. Eisenberg, when a food importer employs your lab to take samples and analyze that for submission to FDA, to satisfy the agencies requirements under import rules, who owns the rights to the results?

Mr.EISENBERG. The importer.

Mr.DINGELL. The importer?

Mr.EISENBERG. We are working for the importer.

Mr.DINGELL. What are the rights of FDA with regard to that information?

Mr.STUPAK. Mr. Eisenberg, put your mic on, would you please, sir?

Mr.DINGELL. Does FDA have the right to that information or not?

Mr.EISENBERG. The FDA, in its procedures, requires that we sign a laboratory director's statement that we are submitting all work that we have done on a sample. And if an FDA district requires that statement we research our records and provide all the work that we did.

Mr.DINGELL. But automatically get that information or not? Is there a great toe dance that goes on before they get it or do they get it right away as a matter of rights?

Mr.EISENBERG. Well, in that situation they would get all of it right away, however, if the importer tells us not to submit the information to the FDA, the FDA never sees it.

Mr.DINGELL. Under what circumstances do they keep this from FDA? When, how and why?

Mr.EISENBERG. Well, sometimes they may want to keep a clean record on their item, on their food item, with the FDA.

Mr.DINGELL. So they don't send it to Food and Drug?

Mr.EISENBERG. That is right. They don't submit—they advise us, tell us, not to submit the work.

Mr.DINGELL. Food and Drug doesn't know what the situation is?

Mr.EISENBERG. That is right. The importer may re-export the product. We don't know.

Mr.DINGELL. And that could be something coming in with salmonella or mercury or——

Mr.EISENBERG. Sure.

Mr.DINGELL [continuing]. PCBs or some kind of bacterial or viral contamination, right?

Mr.EISENBERG. Yes.

Mr.DINGELL. OK. Now, if somebody imports, for example, shrimp from China, which is currently under import alert and you test for antibiotics or fungicides and find excessive levels what happens to your report?

Mr.EISENBERG. If the importer tells us not to submit it to the FDA we don't submit it to the FDA. If we see something that we view as being an imminent hazard to public health, which is very,

very rare, we advise the importer of this and then we check with the importer to make sure that they have reported the problem to the FDA. And if they had not reported the problem, then we would. We had two situations where importers took our laboratory reports and whited out information on our reports that was harmful to the entry of the import. In those cases we had no choice. We went to the FDA and immediately advised them of what had happened.

Mr.DINGELL. So it is perfectly legal for you, then, to discard the analysis without informing the FDA?

Mr.EISENBERG. Yes.

Mr.DINGELL. And you can do that at the instigation or request of the importer. Is that right?

Mr.EISENBERG. Yes.

Mr.DINGELL. All right. Now, the FDA has made a big point to say that it is the private lab, and not the importer, that decides from the place in a shipment, that is which bag, box location in the container, or where in the warehouse the samples are taken. Is it your experience that the importers make such a decision for you and/or for your competitors? They decide which parts of the, you know, the lot from the import that is going to be scrutinized?

Mr.EISENBERG. An analysis is only as good as the sample taken.

Mr.DINGELL. That is correct, because it is not——

Mr.EISENBERG. And if we take a sample we will sign a collection report that we sampled the shipment without bias. We are not saying that we sampled it in a random way. And if we sign that report that we took it without bias then we were responsible for the sampling, and no one directed us as to what the sample, and we did our best——

Mr.DINGELL. But you are never——

Mr.EISENBERG [continuing]. To make sure the sample is representative.

Mr.DINGELL. But you are not required to make a random sampling are you?

Mr.EISENBERG. No. And if you have 40 pallets of product it is unrealistic to ask the importer to bring down all 40 pallets to look at.

Mr.DINGELL. All right. Now, in your statement you say that you lost your Miami business, because you could not—rather you would not give the importers the results they wanted. Would you supply, then, for the records of the committee either publicly or privately the names of the importers that chose to move to less reputable competitors and have you not delivered that kind of information to Food and Drug and the public? To—either publicly or privately? I leave the choice to you.

Mr.EISENBERG. I could try to provide it.

Mr.DINGELL. All right. Don't try to provide it, do provide it. And we will expect to have it.

Mr. Chairman, I am not going to ask that that be inserted in the record, but I do want to have it. I do want to receive that.

Mr.EISENBERG. Our Florida laboratory was a branch operation. I was advised by our manager of the laboratory on various occasions when this occurred, but I was not directly involved. And our manager is now elsewhere, because we closed the Florida laboratory due to lack of business and due to the corrupt situation in south Florida.

Mr.DINGELL. All right. Now, in the same vein, will you please supply us with the names and the circumstances surrounding each instance where you were asked to discard violative findings by a client? You can do that either for the record or privately to the committee.

Mr.EISENBERG. That we should be able to do.

Mr.DINGELL. OK.

Mr.EISENBERG. And we can simply see all the violations that were never reported.

Mr.DINGELL. We would like to receive that, and we will put it in the record or use it in other fashion.

Now, Mr. Rodkin, you did test the lots of Peter Pan peanut butter that were found to contain salmonella that sickened over 600 people. Is that correct?

Mr.RODKIN. That is correct.

Mr.DINGELL. And your microbiologic testing found two jars contained this toxin, but you failed to inform Food and Drug of the finding. Is that right?

Mr.RODKIN. I am not aware of that specific instance. Can you give me the details on that? The timing?

Mr.DINGELL. It was October.

Mr.RODKIN. Of?

Mr.DINGELL. October 2004.

Mr.RODKIN. I am somewhat aware of that situation, but that was prior—I arrived a year later.

Mr.DINGELL. OK.

Mr.RODKIN. So I don't really know the details of that.

Mr.DINGELL. Now, from October 2004 forward your in-house product testing found no salmonella. Is that correct?

Mr.RODKIN. That is correct.

Mr.DINGELL. Now, but CDC identified Peter Pan peanut butter as the source of the 2007 outbreak. Is that correct?

Mr.RODKIN. That is correct.

Mr.DINGELL. Now, in the staff briefings, in the ConAgra testimony of last year, your company blamed the salmonella incident on a roof that leaked for a week over late July and early August in 2006. Is that correct?

Mr.RODKIN. Everything that we know points to water being the source of the salmonella issue. The roof leak was cited as one possibility and the other was a malfunction in a sprinkler system.

Mr.DINGELL. Now, after the hearing was over, however, the committee learned that FDA took jars of Peter Pan peanut butter from ConAgra warehouses in February of last year, that's 2007, and found 14 out of the 130 jars sampled contained salmonella Tennessee. Can you explain why such a large percentage of jars tested by Food and Drug discovered the toxin, but ConAgra's tests did not?

Mr.RODKIN. I am not a scientific expert, but I can tell you that salmonella requires water to germinate, to grow, and it takes time for that to develop. And our product testing had been done on the line when the product was produced. So it is possible to take a significant amount of time for that salmonella to show up.

Ms.DEGETTE. Will the Chairman yield?

Mr.DINGELL. Certainly. I would be glad to yield.

Ms.DEGETTE. That testing that the FDA did though last year was after you fixed the roof and the sprinkler system, correct?

Mr.RODKIN. That testing was on product that had been recalled, not on new product that had been produced.

Mr.DINGELL. So you say this is with regard to product that was recalled and not new product for distribution?

Mr.RODKIN. That is correct. And, in fact, the plant was shut down for over six months and totally redone. We did not just repair the roof. We totally remade the plant at a cost of many, many millions of dollars, changed all the processes. That is a totally different plant today.

Mr.DINGELL. Now, we seem to have a difference of opinion here. FDA said that this was out of the warehouse and was not from samples of the product that was recalled. How do we explain that?

Mr.RODKIN. Our product—my understanding of that timing that you are talking about our plant had been closed, and all product had been recalled, and the FDA came in and tested product that we had recalled. Potentially that came out of a warehouse and was returned to us.

Mr.DINGELL. Now, I am told that the production dates on this particular lot were as late as January 2007, which is some six months after the leak in the roof was fixed. How do we explain that?

Mr.RODKIN. I need to make sure I have my dates right. But all of—yes. All of the product prior to shutting the plant down was recalled, so that fell into that timeframe.

Mr.DINGELL. I don't quarrel with that statement, sir, but I note that some of the jars that FDA labs found positive for salmonella Tennessee had production dates as late as January 2007. Some six months after the leak in the roof was fixed. Now, did ConAgra know of the FDA lab results on April 24, 2007, when your vice president for manufacturing testified before this subcommittee?

Mr.RODKIN. I am not aware of that.

Mr.DINGELL. All right. Does FDA share the results of these kinds of tests with ConAgra?

Mr.RODKIN. That is the normal procedure.

Mr.DINGELL. And when did they do that here? Do you know?

Mr.RODKIN. I do not know that specifically.

Mr.DINGELL. Now, if you got results prior to 4/24/07, then can you explain to us how you can blame a leaky roof for samples which were marked with a production date after the date that the roof was fixed?

Mr.RODKIN. I'm sorry, sir. I am—I do not know the answer to that.

Mr.DINGELL. Now, what other questions.

Gentlemen, thank you. Mr. Chairman, I thank you for your courtesy.

I yield back the balance of my time.

Mr.STUPAK. Thank you, Mr. Chairman.

Ms. DeGette, for questions, please.

Ms.DEGETTE. Thank you, Mr. Chairman.

Now, Mr. Rodkin, I want to thank you for coming personally today. I know it can't be a happy experience for you, and I am not happy myself, because since the beef recall in 2002 we have had

ConAgra in front of this committee talking about E. coli, salmonella in peanut butter. In your opening statement you didn't talk about the popcorn line, but one of those people actually lives in Colorado, my home state. And now here we are with salmonella in the pot pies. And the thing that is frustrating to us, as members of the Oversight and Investigations Committee, most of us have been on this committee for some years now, is every 6 months or a year you folks are in with some new problem. And our constituents are stopping us and saying, what can you do to make our food safer? So it seems to us that many of the industries represented here really are making a good faith effort, including ConAgra, to improve the situation, but it is all done in a reactive way. The peanut butter's contaminated, so you fix the roof. So the popcorn line is making people sick, so you take that additive out of the popcorn, and on and on. What I am interested in, and I think what Mr. Stupak and the Chairman are interested in and the folks on the other side of the aisle, is how can we stop food from being contaminated. And one thing that you talked about and that we have talked about is these recalls, and so let me ask you first about the recalls in the pot pie outbreak and the subsequent recall. Now, ConAgra heard about people getting sick on October 8. Is that correct?

Mr.RODKIN. We first learned of that on Monday, I believe October 11. It was whatever Columbus Day was.

Mr.DEGETTE. OK. So you learned on October 11. And then you said that you immediately issued—that is not right? OK. Staff says that is not right. They are saying it is October, Friday, October 8. But be that as it may, what happened next was there was a consumer advisory issued, correct?

Mr.RODKIN. A consumer advisory was, which means telling consumers not to eat the product, and telling——

Ms.DEGETTE. And how was that disseminated?

Mr.RODKIN. I am not aware of the exact details.

Ms.DEGETTE. OK.

Mr.RODKIN. But I can tell you it was done in conjunction with the USDA.

Ms.DEGETTE. Now, why wasn't a recall issued instead of a consumer advisory, which is the next step up?

Mr.RODKIN. We were working with the USDA and they asked us to do a consumer advisory. The next day——

Ms.DEGETTE. So it was because the USDA asked you to do it?

Mr.RODKIN. We were working collaboratively with the USDA.

Ms.DEGETTE. Well, you know, that is kind of a lawyerly answer. Did ConAgra say to the USDA, well, we think we will issue a consumer advisory, and they said OK, or did the USDA say we want you to issue a consumer advisory?

Mr.RODKIN. The——

Ms.DEGETTE. That makes a difference to me.

Mr.RODKIN. We worked together with the USDA.

Ms.DEGETTE. And you decided jointly to issue a consumer advisory and not a recall?

Mr.RODKIN. The USDA asked us to do that, and we agreed.

Ms.DEGETTE. OK, thank you. Now, at some point then was the—the pot pies were recalled, correct?

Mr.RODKIN. The next day after the advisory we at ConAgra decided there might possibly be some consumer confusion, so we decided to make it a total recall of all of our pot pies.

Ms.DEGETTE. So why did you decide there would be consumer confusion?

Mr.RODKIN. Because we were doing our own analysis and investigation with our customers and consumers, and decided that——

Ms.DEGETTE. What did you think they would be confused about?

Mr.RODKIN. That they might not get the full impact of the advisory, and we wanted to go all the way to a total recall.

Ms.DEGETTE. OK. And so then you recalled all the pot pies?

Mr.RODKIN. Correct.

Ms.DEGETTE. Now, I have introduced legislation the past couple years giving the USDA mandatory recall authority. What is ConAgra's position on that legislation?

Mr.RODKIN. We believe that mandatory recall for any company that is not cooperating is fine. We would agree with that.

Ms.DEGETTE. But you think that the company should have the ability to do voluntary recall first?

Mr.RODKIN. We believe that a company should do what is right.

Ms.DEGETTE. Right, OK. But your answer, again, was kind of a hedge answer, because you said we believe in mandatory recall authority if they don't do the right thing.

Mr.RODKIN. If we are presented with the——

Ms.DEGETTE. But my question is let us say the USDA is presented with a situation where they have a serious problem with some food. And let us say they have a manufacturer who says, well, we are going to do some more testing, we are going to do some different things, and then we will decide what to do. Do you think that the USDA should have the ability to come in and say, this is such a public health risk, we are going to mandatorily recall this product?

Mr.RODKIN. I can't speak for other companies, but——

Ms.DEGETTE. No, I am asking you as the chairman of ConAgra.

Mr.RODKIN. If it was ConAgra and they presented us with that information——

Ms.DEGETTE. No, no. I am asking you should they have the ability to do that? Yes or no?

Mr.RODKIN. For any company that is not cooperating we believe mandatory—we would support mandatory.

Ms.DEGETTE. But if—now, who defines are they cooperating? You, the company?

Mr.RODKIN. In the instance that you just talked about I would consider that not cooperating.

Ms.DEGETTE. OK. Well, who decides that? The company or the USDA?

Mr.RODKIN. The USDA.

Ms.DEGETTE. Thank you. Now, one last thing. I think a lot about this mandatory recall issue, and the problem with mandatory recall is once you—or a consumer advisory, once you are doing it that horse is out of the barn. That product is out there on the shelves, and the mothers are buying the jars of peanut butter and putting them on the sandwiches for their kids. They may not—you know, I tell you they may not see the consumer advisory, which we don't

even know to disseminate it. They may not even know about the recall, so this is my question, and I just want you to think about this. And if anybody else wants to try me, and I would be happy to hear your view. What can we do to beef up the FDA's and the USDA's power in cooperation with industry to make sure that that product is safe when it goes out, so we don't have to rely on recalls, which are a faulty way of getting products back?

Mr.RODKIN. I think it is incumbent upon the industry to act responsibly, and I believe that we have. We have taken very prompt actions as soon as we learned of any issues, spent significant resources proactively. That is time and money to raise our standards, made very proactive precautionary change across the entire company. And, in fact, in our approximate $450 million capital budget, the number one priority on a go forward basis is safety.

Ms.DEGETTE. So you don't really think anything in addition can be done, except for the industry making a commitment?

Mr.RODKIN. I think the primary responsibility is on the industry, and also to cooperate 100 percent are priorities.

Ms.DEGETTE. Because they have done such a swell job so far. Thank you very much, sir.

Mr.STUPAK. I hate to say this to this panel, but we have got votes again. They told us it would be awhile, but obviously they were wrong in their guesstimation. We have got about three minutes left—the votes. And we got a Motion to Recommit, so it is probably going to be 3:15 by the time we get back, so we are going to stay in the recess until 3:15. Other members have expressed interest about asking the panel's questions of this panel. So we are going to ask the panel to hold.

3:15, see you back here at this time. We will stand in recess.

[Recess.]

Mr.STUPAK. OK. The Committee will be back in order.

Let me remind all witnesses we are still under oath. Sorry about the delays. We thought we were just going to have a few votes, and it ended up being more than what we thought. But the good news is we are done with votes, so hopefully we can get this panel done, and we can finish up today. The bad news is the SCHIP hearing is done so members may be coming in for more questions.

Let me go with the questions. Again, everyone is under oath.

Mr. Rodkin, if I may, I hate to continue to bring up this about the salmonella, but we were just getting conflicts in answers up here from facts of what we know. And then as you know this came up at a previous hearing, so we are getting conflicting information.

In response to the peanut butter contamination outbreak has ConAgra gone back and tested products for salmonella on peanut butter?

Mr.RODKIN. Yes.

Mr.STUPAK. OK.

Mr.RODKIN. We certainly have on an ongoing basis with much more rigorous testing in a totally renovated and revamped new plant.

Mr.STUPAK. OK. And in that testing ConAgra found, have they not, they found salmonella in peanut butter produced in 2004, 2005, 2006, 2007?

Mr.RODKIN. The only peanut butter that I am aware of that was tested for salmonella was in 2006. I am not aware of the other dates.

Mr.STUPAK. So you don't know in 2004, 2005 or 2007? You are not aware of it?

Mr.RODKIN. I am not aware of those dates, just 2006.

Mr.STUPAK. OK. For the record would you go back and check with your folks——

Mr.RODKIN. Yes.

Mr.STUPAK [continuing]. And get this thing cleared up once and for all?

Mr. Eisenberg, if I may. In your testimony, page 2, it says the purpose of the PICSC, Pacific Import Community Steering Committee, right, was to provide a conduit for information from the FDA to the regulated import community, and from that community back to the FDA in the public interest to assure and improve FDA's regulation of imports. The three sections would meet three times a year by televideo conference. It says the FDA ended its involvement or sponsorship of the PISCA in early 2006. Is that correct?

Mr.EISENBERG. Yes, that is correct.

Mr.STUPAK. Why did they end this relationship where private industry is trying to work with you and others to detect import problems and imports with food?

Mr.EISENBERG. Well, they advised me that they were meeting with different groups, and that they were creating different groups that they wanted to meet with. And they were no longer interested in meeting with the PISCA group.

Mr.STUPAK. Did they give you any indication of what these other groups—who these other groups were?

Mr.EISENBERG. No.

Mr.STUPAK. OK. Who terminated this? Who did you learn this from at the FDA?

Mr.EISENBERG. Mark Rowe, the acting regional director.

Mr.STUPAK. OK. In a question—in your answer to a question that Chairman Dingell, that because of the corrupt situation in south Florida you closed your office. Explain that.

Mr.EISENBERG. Well, first of all, the FDA had deregulated or was not enforcing their regulations with regard to pesticides residues, especially in snow peas. So a significant part of the market, of the business down in south Florida, had evaporated. It no longer existed. But also we were the first people to open a laboratory in south Florida, and we worked, we spent a lot of money, we tried—we did excellent work. But along the way a gentleman who had actually worked for us for six months left and set up his own laboratory with two leased gas chromatographs. A Dunn and Bradstreet report indicating $68 is the maximum amount of his assets or whatever, and the FDA accepted his reports on an equal basis. And I, you know, his—I cannot prove it, but I do not have confidence that all the work that he did was honest.

Mr.STUPAK. OK. Is your lab certified by the FDA?

Mr.EISENBERG. The FDA does not certify any laboratories. It doesn't accredit. What it has done is it will disqualify labs that it finds due to deficient work.

Mr.STUPAK. OK.

Mr.EISENBERG. And we are not disqualified. We do work nationwide and we are not disqualified.

Mr.STUPAK. Well, when there is an alert and you are asked to test a product, a company comes to you and says I got to get this import alert lifted, I have to test this product. It has to be tested, what three times, before it is allowed to continue on?

Mr.EISENBERG. At least five times, then the importer must file various paperwork that I am not——

Mr.STUPAK. OK.

Mr.EISENBERG [continuing]. Knowledgeable about. Sometimes, though, the FDA may say, well, we are not satisfied with five clean shipments. We want 10 before we even go and review the paperwork.

Mr.STUPAK. Well, whatever the number is.

Mr.EISENBERG. Normally a minimum of five shipments.

Mr.STUPAK. And when you do tests, the test results go to who? The FDA or their client who asked you to do their tests?

Mr.EISENBERG. We generate the results and then we request in writing from the importer confirmation that we should submit the results to the FDA.

Mr.STUPAK. OK. If you do not get a confirmation from the importer what do—are you allowed to ship those results into the FDA or not?

Mr.EISENBERG. We are afraid of—we have a fiduciary relationship to our client, so if they tell us not to submit the results we don't submit them.

Mr.STUPAK. Do you know of any reason why any tests your or any other lab does should not simultaneously, whether it is a positive or a negative, go to the FDA and to the client shipper?

Mr.EISENBERG. I think it absolutely should go to the FDA concurrently with when it goes to the shipper, but this is not the—this is not in the FDA rules at this point in time.

Mr.STUPAK. Right, correct. OK.

Mr. Lischewski, if I may, a couple questions. You indicated in testimony that Castleberry products were recalled due to risk of possible botulism contamination, correct?

Mr.LISCHEWSKI. Correct.

Mr.STUPAK. Aren't there about 90 products that were looked at possibly that might have been contaminated?

Mr.LISCHEWSKI. Correct.

Mr.STUPAK. And, I think, you said in your previous testimony that two products were found to have problems?

Mr.LISCHEWSKI. That is correct.

Mr.STUPAK. And these two products you had the lot codes and you were able to recall what they were. Is that correct?

Mr.LISCHEWSKI. Yes.

Mr.STUPAK. OK. Botulism typically occurs in low acid canned foods when those cans are not heated long enough and to high enough temperatures that kill the spores that could cause botulism, correct?

Mr.LISCHEWSKI. Correct.

Mr.STUPAK. OK. And did you tell our committee staff that botulism contamination on your products occurred when certain prod-

ucts were not heated to a high enough temperature to kill the spores which cause botulism?

Mr.LISCHEWSKI. Yes, that is correct.

Mr.STUPAK. OK. And is it true that under the heating process was caused by a malfunction of a valve at the bottom of your retort system? A system that heats the canned foods?

Mr.LISCHEWSKI. Yes.

Mr.STUPAK. And because of the type of food that you produce both FDA and USDA would be in your Augusta, Georgia plant where this botulism problem may have occurred, correct?

Mr.LISCHEWSKI. USDA was at the factory every day.

Mr.STUPAK. USDA.

Mr.LISCHEWSKI. But FDA was also there. We produce products and they are both jurisdictions, but FDA only comes on an inspection basis.

Mr.STUPAK. OK. This malfunctioning valve, explain that to us. If FDA's there and if that is one of the areas or USDA—if that is one of the areas you check, I'm curious, why didn't anyone catch it?

Mr.LISCHEWSKI. The valve basically, the type of equipment that we used for sterilization, is produced by a company called Malo. And what happens is these tanks are full of water, product—canned product goes in, water is pumped out——

Mr.STUPAK. Correct.

Mr.LISCHEWSKI [continuing]. Through this valve and steam is applied to sterilize.

Mr.STUPAK.

Mr.LISCHEWSKI. The malfunction of the valve allowed some water to stream back into the bottom of the container such that some of the cans were submerged in water. The design of these particular retorts did not allow for any reporting of temperatures at the bottom of——

Mr.STUPAK. How about visually? I mean visually wouldn't you see the water in the cans?

Mr.LISCHEWSKI. No, these are stainless steel containers.

Mr.STUPAK. Right, these retorts.

Mr.LISCHEWSKI. You can't see inside of them.

Mr.STUPAK. OK.

Mr.LISCHEWSKI. So, again, normally we look at pressure gauges and we look at temperature gauges to monitor the performance of the retort. The small amount of water in the retort didn't allow us to see any deviations in the pressure. And the fact that there weren't temperature gauges throughout at the bottom of the container we couldn't see the difference in temperatures.

Mr.STUPAK. So in your situation it was both the water plus temperature?

Mr.LISCHEWSKI. Correct. The fact that cans were in the water——

Mr.STUPAK. Right.

Mr.LISCHEWSKI [continuing]. And the steam was going onto the regular cans, but that particular water caused a partial sterilization. So that when we went through our normal quality protocol post processing where we normally would have picked up an under processed product the fact that some heat had been applied meant

it went through our normal process, and didn't basically grow the botulism bacteria until after it has been released.

Mr.STUPAK. So when your finished product was done——

Mr.LISCHEWSKI. Yes.

Mr.STUPAK [continuing]. Before you shipped is there testing then that you do?

Mr.LISCHEWSKI. Yeah, we basically——

Mr.STUPAK. Or does it——

Mr.LISCHEWSKI. Once the product is finished, the day after processing, we do an organ analeptic evaluation of the product. And we also put the product on a three day incubation, so if a product had not been sterilized then that product would swell and we would pick it up before it ever went into our distribution channel. Given that it was partially sterilized and there were no control mechanisms within the Malo retort that allowed us to see that or see variations that product actually made it through our process.

Mr.STUPAK. And you said swell. You mean the can itself would swell?

Mr.LISCHEWSKI. The can itself. If it wasn't sterilized the protein inside would swell and you would be able to notice it in the product.

Mr.STUPAK. And that would occur within three days?

Mr.LISCHEWSKI. Yes.

Mr.STUPAK. OK.

Mr. Ray, let me ask you then, because in the FDA reports I saw you actually had swelling in the cans from what the FDA said. Right in front of you is a book there, sir. You may want to go to Tab No. 41. This is—and the reason why I want you to go there is it is form No. 483 of the FDA. Because in your testimony you stated our investigation is still underway and we have not yet determined—have not yet—excuse me. Have not yet received key information from the FDA about their findings. But when I look at this reform here, this form 483——

Mr.RAY. Um-hum.

Mr.STUPAK. It looks pretty clear to me. You received form 483, right? You are familiar with that form?

Mr.RAY. Yes, we did on February 15.

Mr.STUPAK. OK. And the FDA confirms that botulism spores were found in four cans, correct?

Mr.RAY. That is correct.

Mr.STUPAK. OK. And is it not true that the botulism spores were found in four water wells that the company uses?

Mr.RAY. That is correct.

Mr.STUPAK. OK. And before you use these water wells didn't you use to use water that was treated with chlorine?

Mr.RAY. That is correct. Well, we used——

Mr.STUPAK. Chlorine would kill the botulism spores, right?

Mr.RAY. No, that is not correct.

Mr.STUPAK. OK. But, OK, so they found it in cans and they found it in the wells. Then the company used the water from these wells to cool the cans after they have been cooked, right?

Mr.RAY. That is correct.

Mr.STUPAK. OK. Then is it not true that the FDA believes that botulism spores entered the cans through loose seams after being cooked while the cans were being cooled?

Mr.RAY. That is correct. You had asked about the chlorination. The chlorination for the drinking water levels would only be probably one to two parts per million.

Mr.STUPAK. Sure.

Mr.RAY. To actually destroy the C.bot spore——

Mr.STUPAK. Sure.

Mr.RAY [continuing]. It would have to be probably 10 to 20 times that.

Mr.STUPAK. But to use these wells you had to check to see if they contained any spores or any bacteria that might be harmful in your food process did you not?

Mr.RAY. No, we did not. That is not normal process. We would do potability testing. We would test the water every four months and return the information to the district health department.

Mr.STUPAK. Then how did the botulism spores then get in these four wells then?

Mr.RAY. We did not anticipate or did not test for—in history prior to FDA drawing samples we had never tested, nor is it industry practice, to test—to have botulism in water wells, or botulism spores, I should say.

Mr.STUPAK. The FDA stated that the post process botulism contamination in low acid canned food products has only occurred about four times since 1940. It is very rare for this to happen.

Mr.RAY. Right.

Mr.STUPAK. But the FDA determined that you manufactured multiple lots of low acid canned foods with lose seams, and that was—and the company was aware of the lose seams before the FDA investigation was it not?

Mr.RAY. No, we were not, sir.

Mr.STUPAK. Well, in that form right there at observation #6.

Mr.RAY. OK.

Mr.STUPAK. Does it not indicate that the company was aware of the lose seam problem?

Mr.RAY. Observation #6. The observation I see in front of me was that the FDA came in and made an observation that they felt that some of our technicians were not properly evaluating the double seams.

Mr.STUPAK. Right. And that, therefore, you didn't have any many as you should have in these cans which would cause problems with it?

Mr.RAY. As many—I don't understand the question.

Mr.STUPAK. You were supposed to have somebody crimping the cans are you not?

Mr.RAY. Well, the condition of the seam itself is evaluated by a technician.

Mr.STUPAK. And you didn't have a qualified individual who could detect that. Is that not what they found?

Mr.RAY. We felt—they—we felt we had qualified technicians.

Mr.STUPAK. You felt that, but the FDA did not?

Mr.RAY. That is correct.

Mr.STUPAK. OK. In your testimony you stated that botulism spores are regarded as so unlikely to be found in water that testing was not a standard procedure. But isn't there a regulation that states that low acid canned food manufacturers must chlorate their water or sanitize the cooling water used in the process?

Mr.RAY. I believe it does depending on the use of the water, sir.

Mr.STUPAK. And it is also on that finding that you didn't consistently do this. Either use the chloride water or sanitize cooling water used in your process, correct?

Mr.RAY. There was a point in time that our former quality service manager had through some corrosion studies ceased using chlorine. That was a mistake.

Mr.STUPAK. Right, it is observation no. 7 there. So the bottom line on this whole thing was number one, you didn't have a qualified person to check on the cans and the crimping that which led to lose seams, which is susceptible to botulism contamination. And you didn't treat or test the water that might enter the cans through these lose seams, which could have lead to botulism, correct? Those are the two findings of the FDA.

Mr.RAY. Well, I think the one thing to make clear about is that chlorination, that the chlorination of drinking water, it was not sufficient enough to destroy the C. botulism spores.

Mr.STUPAK. Well, again, looking at Exhibit 41 there, here is what the FDA observed. That you failed to properly evaluate defective lots in a timely manner to assure that there are no potential public health hazards associated with your finished products. Your firm's employees did not conduct a complete spoilage diagnosis to determine whether spoilage was due to under processing or post process leakage. Corrective action was not taken in a timely manner to remove and destroy defective spoiled cans, to fix the problem causing the spoilage, whole or portions of effective lots were observed with swells, buckled or defective seams in the warehouse. Isn't that correct?

Mr.RAY. That is what the work order says, sir.

Mr.STUPAK. You don't feel your company was responsible for that? Well, I think I would like to ask—maybe you don't want to admit it.

But Mr. Lischewski was telling us about the can would swell within the three days. Your company actually had employees take the swelled cans and put them in a process where they pressed the can back to basically hide the swollen cans, right?

Mr.RAY. We had debuckled—back several years ago there was some debuckling of cans by some employees. I think in 2005.

Mr.STUPAK. Well, according to the FDA your firm, and again I am reading from the report now, reshaped cans of LACF products that exhibited evidence of buckling by using a hand press to push the can ends back into place. These debuckled cans were then released from the hold status and made available for sale to your customers. Isn't that true?

Mr.RAY. That is correct.

Mr.STUPAK. So I mean if you didn't know about the water, you didn't know about crimps or the seams, you certainly knew about the buckling. You certainly knew you had a problem, but you continued to sell them to your customers.

Mr.RAY. The circumstances of what you are talking about were two very different points in time. The buckling of the cans occurred based on recommendation of our can supplier back, I believe, in 2005. The situations in which we are talking about in these observations are defective lots that were—observation 1C, for example, that we had defective lots that we did not handle on a timely basis. Those defective lots were lots that we had identified as processed deviations.

Mr.STUPAK. Right. But this is from November 26, 2007 to February 15, 2008, top right-hand corner. I mean that is when this report is, and that is when they found these cans and your debuckling.

Mr.RAY. We would to—I'm sorry, sir. Could you repeat the question?

Mr.STUPAK. Sure. You said that they were from some time, but this report, this 483, Exhibit——

Mr.RAY. Um-hum.

Mr.STUPAK [continuing]. Report 483. Actually date of report is 11/26/2007 it looks like 2/16/2008, right?

Mr.RAY. That is correct.

Mr.STUPAK. So these findings were during that period of time, so they weren't from 2005.

Mr.RAY. The debuckling was from a prior time.

Mr.STUPAK. So you still had the cans on the premises?

Mr.RAY. No, we did not, sir. We had them at a prior time.

Mr.STUPAK. Mr. Lischewski, the buckling of cans and them pressing them back is that a standard procedure within the industry?

Mr.LISCHEWSKI. No.

Mr.STUPAK. OK. Mr. DeLorenzo, let me ask you this. We had testimony here—and I think last we were talking about E. coli spinach and lettuce and all this. That we have had about 20 outbreaks in the Salinas Valley within the last 10 years, correct?

Mr.DELORENZO. I am not sure how many.

Mr.STUPAK. Somewhere around there. About every 6 months we seem to have one of these. I'm sorry. You got to turn on your mic. Has Dole—you are the largest producer in that area, or processor. Have you done anything to try to figure out what is going on here? It seems like if you have one of these salad problems, E. coli, problem, every 6 months you want to do something. I mean I have asked the FDA the same question, and they just look at me like, you know, what to do. I mean an epidemiology study I have suggested to them. Have you suggested anything like that?

Mr.DELORENZO. Yes. I think the industry is desperate to make sure there are no more incidents or recalls. As I described, the industry got together and has put a very, I think, significant food safety processing and protocol in place for the farming and processing. I personally co-funded just a few months ago a seminar here in Washington, because I wasn't satisfied either with the answers that we are getting. That this E. coli is prevalent and nobody has a kill step, and nobody is exactly sure where it is coming from. So we had a seminar——

Mr.STUPAK. And what did you learn from that seminar?

Mr.DELORENZO. I learned that we——

Mr.STUPAK. No answer?

Mr.DELORENZO. No answer. We had 70—we had approximately 70 scientists from Academia. We had the USDA, FDA scientists. And my, perhaps naively, agenda was to come away from that after two days of being here with all these people who had studied this for many, many years, mostly out of the meat industry—that is where most of the E. coli studies have come from. Basically what they—the conclusion was A, that they are not sure where it comes from. Obviously cattle is the primary—cattle droppings is the primary cause. They are not sure how it migrates. They are not sure how it lives, is able to live in the environment that we have. They are not sure how it avoids the kill step in the chlorine wash that we have.

Mr.STUPAK. Well, then we would—irradiation that we talked a little bit about today. Would that help solve this problem in the Salinas Valley?

Mr.DELORENZO. We have an irradiation—we had an irradiation expert from, I think, he was from Texas, and we are still working with him. Unfortunately, with irradiation of fresh produce it tends to cook the product so we haven't gotten over that one yet. But we are actually going to be funding some work that he is going to be doing. And I will admit it is very, very disconcerting when it comes to E. coli.

Mr.STUPAK. Well, let me ask you this. The produce industry had called on the FDA to enter tough new regulations regarding the handling of fresh produce; however, the FDA has not done this. It has been reported that earlier this year the FDA came up with new regulations on handling of fresh produce. These regulations were intended to replace existing voluntary guidelines. That is what is in place now, right? And according to the Wall Street Journal, May 16, 2007, the FDA proposal, and I am quoting now, went nowhere after it got a cold reception from the Department of Health and Human Services. The article states the FDA plan, which would have cost $76 million over three years was rejected after it was presented in February at HHS headquarters. Would you want to see mandatory regulations?

Mr.DELORENZO. Yes, I would.

Mr.STUPAK. OK. Were you involved in helping to put together any of these mandatory, or Dole or anyone, putting together these mandatory regulations that were presented to the secretary in 2007?

Mr.DELORENZO. Let me—do you mind if I just ask a question, because I wasn't——

Mr.STUPAK. Sure.

Mr.DELORENZO [continuing]. At the company at that time? I guess we were involved indirectly through the trade groups, and then directly in California with the Leafy Greens Agreement that the industry put in place.

Mr.STUPAK. OK.

Mr.SHIMKUS. Can I——

Mr.STUPAK. Sure, go ahead. Jump in. Mr. Shimkus wants to jump in, and we might go back and forth here for a bit. Go ahead.

Mr.SHIMKUS. I was just going to give you a chance to get your breath.

Mr.STUPAK. I am just getting warmed up. Go ahead.

Mr.SHIMKUS. That is what I am afraid of. The—just going back, Mr. DeLorenzo, just on the timeline. The spinach that we are talking about, you were a purchaser of that, correct, and then have you now changed the processes where you are the producers now? It is more in-house where you are attempting to try to get control?

Mr.DELORENZO. Yes, we agree.

Mr.SHIMKUS. That is kind of the timeline then I heard.

Mr.DELORENZO. Right. We are taking everything in-house now.

Mr.SHIMKUS. And that—why are you doing that?

Mr.DELORENZO. Well, I am doing it more just to make sure that we have complete control over the processes. And I am not trying to blame the other company, because I think it was a reputable company. But there is enough—in the fresh business there is enough variables that I just felt it was important to have everything in-house.

Mr.SHIMKUS. I mean I heard that in the opening and the questions, and I think that when you—I mean you have better control of the operation when it is yours. And obviously there are risks in——

Mr.DELORENZO. Can I jump in?

Mr.SHIMKUS. Yes.

Mr.DELORENZO. Are you talking about the Natural Selection one? The hearing we had last time, Natural Selection?

Mr.SHIMKUS. Yes.

Mr.DELORENZO. Natural Selection have seen then testified that they have gone through and testified the leaf as they process it now.

Mr.SHIMKUS. Yes. Did you do that or do you still rely upon Natural Selection or——

Mr.DELORENZO. We are doing our own testing. As I said since that incident we have done over 4,000 tests on our products both field and in processing, and so far they have all come up negative.

Mr.SHIMKUS. OK. What you and Natural Selection are doing, is that the exception to the rule or do most producers now do that?

Mr.DELORENZO. No, I think most producers. The Salinas Valley is very, very motivated to eliminate this problem, because every farmer's livelihood is based on this. And so I think that there has been a very good industry movement. More than I——

Mr.SHIMKUS. OK. Natural Selection said they were the only one, you would be second. So this would all be since September of 2007, I think, was the last recall.

Mr.DELORENZO. I am not sure how much testing every company is doing, but I am pretty sure all the large companies are testing.

Mr.SHIMKUS. Thank you.

The—Dr. Brackett you have been on the end there, quiet, and just a couple questions to you. Mr. Eisenberg testified that when you were assistant and director you advised, in June 2006, that FDA would no longer monitor pesticide residues in foods because the agency did not consider the residues a serious matter. Can you comment on this?

Mr.EISENBERG. Yes, Mr. Shimkus. I am glad I have the opportunity to respond to that. In fact, I never did say that we didn't consider it a serious matter. Any violation of the law was a serious

matter. And it wasn't just IFT, but in other locations I said with the limited amount of resources we were going to focus on those things that had the biggest public health impact at that time. So if it was a matter of testing for something that was killing children, like E. coli 157H7 or a violative pesticide, we were going to go on saving children.

Mr.SHIMKUS. Mr. Eisenberg, you state you lost business because of this. Can you restate that for us, please?

Mr.EISENBERG. I'm sorry. Can you repeat the question?

Mr.SHIMKUS. You—I am just restating that you, because of the decision, you closed down operations, lost business. I mean I am just——

Mr.EISENBERG. That is correct. The FDA had substantially reduced the number of shipments that it stopped for detention without physical examination, analysis and sampling. And then what little work was left was being taken by a laboratory that we could not compete with.

Mr.SHIMKUS. Mr. Brackett, based upon the testimony you have heard today, do you believe that the case studies and, you know—that is what we have in a multitude of different aspects. Do you believe that the case studies are representative of general problems found in the food processing arena?

Dr.BRACKETT. Well, I think it is a good selection of the type of problems that could be found. You have got a variety of different commodities oriented here, and they all have similar—well, they all have differences because of the science involved, but they all have some similarities too, and they all point to five different things that we can think of. One of which is that we have got to resource the regulatory agencies so they can oversee the industry the way that would help them. Secondly, we think that it would help if the industry as a whole was mandated to have a plan where they actually looked down the line what was going to happen and then had remediation steps to deal with those. Thirdly, also to be able to, as Mr. DeLorenzo said, we do believe that they should have some sort of mandatory baseline safety rule for produce industry, again, to make sure that that is taken care of. And secondly, also, which was in our pillar one at the Grocery Manufacturers Association, to make sure that importers require of the companies that are importing to them documentation of the safety practices that they are engaged in so that we can facilitate commercial. And then of course part of this that we have talked about too is supporting mandatory recall when the manufacturer delays or refuses to do it.

Mr.SHIMKUS. And finally, just going back, Mr. Brackett, and you kind of mentioned it on the import end, because on the first panel we had the—Mr. Williams talked about some of those challenges that they are facing. Anything in that first panel that you could respond to, to help clarify some of the testimony there?

Dr.BRACKETT. With respect to which part are you asking?

Mr.SHIMKUS. Well, I mean obviously formerly with the FDA there was a lot of—while you served, you know, there. And I was just giving you the opportunity to respond to anything that you thought that you may need to respond to out of the first panel.

Dr.BRACKETT. Well, I think out of the first panel probably what Mr. Marler said was probably the most significant is there is a lot

of calls for regulations, and while I was there were called for regulation standards, and in some cases they are needed. But a regulation based on no or bad science is going to be more problematic for the industry than putting something out there. We do have to have more science. We need to have that as a foundation of our regulations, but there are things that we can do now, and some of the things I just mentioned a moment ago are some of them.

Mr.SHIMKUS. Thank you, Mr. Chairman.

Mr.STUPAK. Thanks.

Mr. DeLorenzo, if I may, 2005 Dole had a recall. What was that on? Spinach? Do you know? E. coli? It was something. I forget what it was.

Mr.DELORENZO. We did have a recall on E. coli in 2005 also.

Mr.STUPAK. Was that on spinach or lettuce or——

Mr.DELORENZO. No. I think it was other leafy greens.

Mr.STUPAK. OK, OK. In your testimony you gave me the impression that Canadians had a recall on your product there in 2007, possible E. coli, on packaged salad. And you didn't believe the Canadians or——

Mr.DELORENZO. No, we——

Mr.STUPAK. I got the impression. I mean——

Mr.DELORENZO. No, no, no. We immediately had a recall. What happened is that when you have a—when we had the recall we pulled in product and we tested everything that—all product that came in from consumers.

Mr.STUPAK. Right.

Mr.DELORENZO. From the Canadians that they had, and from whatever products we retained in the plant. Whenever we run the plants we retain products off the line——

Mr.STUPAK. Right.

Mr.DELORENZO [continuing]. So that we have the bags that we can go back to. So all of those came up negative. There was no sight of the E. coli. There was also no sign of E. coli when the different federal and state agencies came through and the Canadian government came through. Our plants and our farms. So the only thing I said is it remains a mystery of where this came from and how it happened and how we could prevent it again. And so there is a possibility it could be a laboratory error. That is always a possibility, but we are not taking it as a laboratory error. We are saying that science says that this is possible. There could be one cell out there——

Mr.STUPAK. Right.

Mr.DELORENZO [continuing]. In one bag at any time.

Mr.STUPAK. Well, the——

Mr.DELORENZO. That is what we really need to do the research.

Mr.STUPAK. And I think that is a good point based upon your earlier testimony. This Canadian example, because all this costs, all the follow-up with bags that were out there could have been a laboratory error, right?

Mr.DELORENZO. It is always possible, yes.

Mr.STUPAK. I mean so there—that was a huge response.

Mr.DELORENZO. Yeah. I think that one thing that we would like to do in any regulation is that I think that there should be transparency on both the regulating side and the company's side. I think

the company's records should be an open book on any kind of—we did ask the Canadian government if we could go look at the tests just to double check them.

Mr.STUPAK. Right.

Mr.DELORENZO. And we weren't allowed access to it. But that is—we are not saying it wasn't.

Mr.STUPAK. Well, have you ever done a recall and then found out later the tests were all wrong? I mean before there is a recall, let us face it, there are tons of tests, right?

Mr.DELORENZO. Well, in this case there was just one bag of—they had——

Mr.STUPAK. OK.

Mr.DELORENZO. As I understand it there is a number of bags of lettuce that they did, and in one bag they found E. coli. And when we went back to double—we did go back and asked can you do more testing on that bag, but there was nothing left. They said it had been destroyed.

Mr.STUPAK. Well, let me ask you this. Because you said in your testimony, you talked about Dole's testing for pathogens. You said you test for pathogens in the field prior to harvest. You test pathogens that enter your processing plant, and you test produce as it leaves as a finished product. How many companies do that? I mean you got three testing processes going on here, right?

Mr.DELORENZO. And we test water also in the field.

Mr.STUPAK. OK.

Mr.DELORENZO. So it is four.

Mr.STUPAK. All right.

Mr.DELORENZO. Let me—may I just ask our——

Mr.STUPAK. Sure.

Mr.DELORENZO. He is saying that all of the major—he believes that all of the major vegetable companies in the Salinas Valley are doing it.

Mr.STUPAK. That is all since about 2007 then, right?

Mr.DELORENZO. Yes.

Mr.STUPAK. OK.

Mr.DELORENZO. Since the spinach.

Mr.STUPAK. When you test the water do you test the water you use in other countries? I mean some of your products come——

Mr.DELORENZO. Yes.

Mr.STUPAK [continuing]. From Mexico and other areas.

Mr.DELORENZO. Yes.

Mr.STUPAK. OK. Mr. Brackett, just a couple of questions if I may. You were at the FDA and the agency essentially, from our point of view, set back in a passive position and relied on companies to follow voluntary guidelines to ensure the safety of food. Do you believe in relying on voluntary guidelines is still a sufficient means to protect our Nation's food supply?

Dr.BRACKETT. Well, Mr. Chairman I think it depends on what you are talking about the voluntary guidelines do. I think there is a role for a baseline set of mandatory standards that can be done if you have got the scientific information done. But then there are——

Mr.STUPAK. But what do we have right now? We have voluntary standards, right?

Dr.BRACKETT. Well, there are still some——

Mr.STUPAK. As a general rule it is a voluntary standard.

Dr.BRACKETT. Food, Drug and Cosmetic Act. So——

Mr.STUPAK. Right.

Dr.BRACKETT [continuing]. For adulterated food that is mandatory. The specifics is where really guidance fits in better and where you are going to have a change in some of the knowledge. That is where guidance needs to be used.

Mr.STUPAK. So is—you are now with the Grocery Manufacturers. Are you for voluntary or do you want to see mandatory guidance in this area?

Dr.BRACKETT. Both. I think that there is a place for mandatory standards on which you place voluntary guidelines.

Mr.STUPAK. OK. So Grocery Manufacturers, like Dole is doing right now.

Dr.BRACKETT. Um-hum.

Mr.STUPAK. They are testing the field, testing the plant, testing the finished product and they test all water sources. Do you think that should be mandatory or voluntary?

Dr.BRACKETT. No, I don't think that part should be mandatory. I think that——

Mr.STUPAK. Why not?

Dr.BRACKETT [continuing]. Testing is sort of a mistaken way of protecting the product if you have no other preventative controls to rely on.

Mr.STUPAK. What point should it be tested then?

Dr.BRACKETT. Well, I think——

Mr.STUPAK. If it is not in the field, if it is not in the processing plant, if it is not in the water, if it is not in the finished product, where should we test it?

Dr.BRACKETT. Well, the place for testing that is not the issue here. The issue is it shouldn't become contaminated in the first place. The work has to be done to prevent contamination. If you have no kill step, if you have no other way then you should be testing the water and——

Mr.STUPAK. But we don't live in a perfect world.

Dr.BRACKETT. No.

Mr.STUPAK. OK.

Dr.BRACKETT. But until we get to a point where we can use irradiation or something else there is a role for testing, but being——

Mr.STUPAK. Well, what testing would your organization, Grocery Manufacturers Association, what testing would you support? I mean the only testing we really have right now are people getting sick.

Dr.BRACKETT. Well, that is right, and we can't have people getting sick. But the point is, is that testing is such a prescriptive action that if you mandate that, any particular type of test, that prevents better tests from being developed. We want whatever is used to be the very best that science provides, and that is a moving target.

Mr.STUPAK. It is a moving target?

Dr.BRACKETT. Right.

Mr.STUPAK. So these 91 recalls we have had in the last 14 months since it is a moving target we can continue to expect it?

Dr.BRACKETT. No. I think we need to drop that. I want to Mr. Marler out of business. The way you use testing is in conjunction with the regulations that you talked about together with the best processing practices that you talk about. There is a role for testing, but putting that into a rule is not the most appropriate use for it.

Mr.STUPAK. And you can't articulate what testing should be?

Dr.BRACKETT. Well, you should—well, there is different. There are five different ways that you can test. You can test for quality standards. That is not going to help you. You can test for a specific pathogen. You are going to miss some and it is going to get out there, and then consumer confidence is going to be eroded again.

Mr.STUPAK. Sure.

Dr.BRACKETT. So you want to have a series of barriers. You want to have prevention. You want to have preventative controls to eliminate them. You want to have the testing to make sure that those are working.

Mr.STUPAK. And whose responsibility should that be? The government or the manufacturers of this?

Dr.BRACKETT. That should be the manufacturers. We are responsible for the product.

Mr.STUPAK. Would you agree with the Science Board when they recently testified before the committee that the FDA does not have the capacity to ensure the safety of the food for our Nation?

Dr.BRACKETT. Well, let me just state for the record also that being an employee of GMA now I can't really respond from the FDA's side. What I can say is that the FDA's comprised of some of the most talented people I have ever worked with, and they have every bit of ability to do something. If you have more than one something at a time, and that is where the races are done, they spend probably more time than they need to responding to things, rather than being able to plan ahead and build a system that they would like to build.

Mr.STUPAK. Right. So Science Board says they don't have the capacity to protect our Nation's food supply. Do you agree with that or not?

Dr.BRACKETT. Again, they have the ability to protect one event, or maybe two, but when you build—or protecting is not the same.

Mr.STUPAK. Do they have the ability to be pro-active?

Dr.BRACKETT. They have the knowledge and the ability. They don't have the resources to do that.

Mr.STUPAK. I asked Mr. DeLorenzo about the Wall Street Journal article and FDA's proposal went nowhere. Did you present that to the secretary of Health and Human Services at the time in your role as FDA?

Dr.BRACKETT. Yes, I did, and in fact that was a proposal. That was at a time when we noticed the number of outbreaks of produce related illnesses going up. And it was an informational meeting. We went and presented this to the Department of Health and Human Services and provided several different options that could be done, one of which was mandatory standards. We also made sure that we——

Mr.STUPAK. So what happened to mandatory—why did mandatory standards get turned down?

Dr.BRACKETT. Well, it wasn't turned down. That was not a decision making meeting. It was really to lay out before HHS what the problem is, what some of the solutions might be, and then that is the point at which——

Mr.STUPAK. Well, did you expect HHS to get back with you then with the options that were laid out at that meeting?

Dr.BRACKETT. At some point, yes,

Mr.STUPAK. Have they ever responded? HHS ever respond back?

Dr.BRACKETT. Well, there was never a response back for that. What happened in the intervening time is we had other outbreaks that occurred. In the meantime we had melamene, we had all of the other things——

Mr.STUPAK. Well, wouldn't all these other outbreaks then reinforce your request to the secretary of HHS that you have some mandatory standards if you are having more and more outbreaks? As the problem was growing wouldn't you go with your strongest recommendation as opposed to not?

Dr.BRACKETT. Well, I think at that point that was something that we needed to enter in the discussion. We had no idea exactly what that meant to our regulation, other than the fact that there had to be some baseline level of mandatory protection for our produce.

Mr.STUPAK. Was the implementation of $76 million to implement this program over three years? Was that one of the reasons why it was rejected?

Dr.BRACKETT. Well, it wasn't rejected. We presented it before them. And I asked our staff when we prepared that plan to put a budget and a timeframe together so that decision makers would know what it would take to do it right and what resources would be required in a timely way.

Mr.STUPAK. Let me ask you this. We are talking about regulations here. The Food Safety Inspection Service has announced plans to change its policy in identifying co-signees in a food recall, but the rule seems to have become bogged down in the bureaucracy at the United States Department of Agriculture and the OMB. Is the industry, Grocery Manufacturers, fighting the rule and what are the merits and problems with telling customers that they may have potentially dangerous food on their shelves?

Dr.BRACKETT. Well, I have to be honest I am not familiar with that whole issue. A lot of that happened before I came to GMA, so I am going to have to defer on that.

Mr.STUPAK. OK. Is there someone in your organization who could comment on that?

Dr.BRACKETT. There would be, but I am not sure who the best person is. I can get that information to you, Mr. Chairman.

Mr.STUPAK. OK. Well, let me ask you one more. A statement by Mr. Eisenberg bothered some of us on the committee. He told us in his testimony that twice during 2005 he met with the senior FDA staff. The second time with Margaret Glavin, Associate Commissioner for Regulatory Affairs, to complain the FDA was not adequately enforcing its pesticide residue requirements on snow peas imported from Guatemala. You are familiar with that?

Dr.BRACKETT. I—yes.

Mr.STUPAK. OK. The testimony goes on to say I presented the data for 25 samples that they had taken at a retailer in the greater Miami area during 2004 and analyzed with 13 being violative of FDA standards. I pleaded with the FDA to take more surveillance swabs and then to place violative shippers on the import alert status as they had done in prior years. Even though the FDA had found a high percentage of violations itself the result of my pleading was FDA reduced by 50 percent the number of surveillance samples analyzed. Does this represent the FDA sort of surrendering in the war against unsafe food imports from other countries?

Dr.BRACKETT. No, I don't think it represents surrendering. I think it really represents a prioritization under limited resources. Again, having the right amount of resources to both food safety as well as pesticide analysis. And again, what I said, making sure that we put some plans in place to make sure that we can document what is being done in other countries to make sure that those pesticides are not applied. But again, it ultimately comes down—and I am not sure why Ms. Glavin made that decision. But it probably had to do with fact, what are you going to do with your resources? Are you going to spend it on something that is immediately public health significance or something that is a violation, a technical violation, of the regulation?

Mr.STUPAK. Should the FDA—and I am asking you because you were there for quite awhile. Should the FDA be encouraged to apply strict liability standards to food processing operations? Specially should executives be criminally prosecuted for repeated failures to supply food free of contamination to their customers?

Dr.BRACKETT. No, I don't think that that is going to make the food supply any safer at all. As was stated earlier by some of the others it is really bad business for companies to be involved in outbreaks. If, unless of course, the person has knowingly and wantonly allowed a product to go out in——

Mr.STUPAK. Well, what about those cattle today? Downer cows? So far two people who were at that plant have been charged. The people working in the yards, but no one higher up is taking any responsibility for this.

Dr.BRACKETT. Well, not being familiar with the USDA side, but I really can't comment other than that they violated the law and legal action was taken.

Mr.STUPAK. OK. I can go a little longer if you want me too. OK.

I think that should probably conclude this panel for now. I don't see any other members present. But I should also note for the record that during our hearing today FDA sent out yet another recall notice on imported fish products that may be contaminated with botulism spores. So we have yet another recall to add to our charts.

And with that I will dismiss this panel. Thank you very much all of you for being here. Some of you even promised us some information. We look forward to seeing it as we will continue our hearings on food and drug safety. With that I will dismiss this panel. Thank you all for being here.

I want to thank all of our witnesses for coming today and for their testimony. I asked unanimous consent that the hearing record will remain open for 30 days for additional questions for the record.

Without objection the record will remain open. I ask unanimous consent that the contents of our document binder on the desk there be entered in the record. Without objection the documents will be entered in the record.

That concludes our hearing. Without objection this meeting of the subcommittee is adjourned.

[Whereupon, at 4:30 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF HON. GENE GREEN

Mr. Chairman, thank you for holding this hearing today on food contamination in the private sector. I think it is important that we continue to have these hearings to address the issue food contamination in the US.

Each year in the US there are approximately 76 million cases of foodborne illness and in the past year there have been numerous high profile food product recalls involving meat, fish, and vegetables.

This committee has held numerous hearings on the issue of contaminated food and the safety of our food. These hearings have continuously highlighted the fact that the FDA and industry need to do more to make sure our food is safe to eat.

While the hearing today focuses on incidents in private sector and industry responsibility, I want to point out that the FDA needs to improve their food inspection system. I believe that many of the outbreaks that have recently occurred can be directly linked to a poor inspection system.

During these hearings on food safety, I have spoken many times of the need for more FDA inspectors at our ports. I represent the Port of Houston and I actually spent one day on the docks as they unloaded cargo and saw how the products are inspected.

It is clear to me that the FDA does not have enough inspectors to inspect the food and products that are entering our country.

If the FDA needs to hire third party inspectors or partner with another agency like the Department of Agriculture, then the FDA should do so to ensure product safety.

It is our responsibility to make sure that the FDA has the resources it needs to protect us from contaminated food products. We can't point out the problem without offering some solution as well.

If we need to provide more funding to allow the FDA to do its job then we should do just that. Consumers should be able to purchase food without having to worry about botulism, E. coli, salmonella, or pesticides in their food.

I want to thank our witnesses for appearing before the committee today and thank you Mr. Chairman for holding this hearing. I yield back my time.

REP. JAN SCHAKOWSKY
OPENING STATEMENT
O & I HEARING
CONTAMINATED FOOD: PRIVATE SECTOR ACCOUNTABILITY
FEBRUARY 26, 2008

Thank you, Mr. Chairman, for your dedication to this issue. The series of hearings that you have convened on food safety in this Congress have revealed a number of truly shocking revelations, and I hope they will serve as wake up call to the companies which manufacture the food we eat and those agencies tasked to regulate them that they must take food safety more seriously.

Jars of Peter Pan peanut butter containing salmonella. Cans of green beans containing botulism. Spinach tainted with E. coli. Poisoned pot pies. The largest meat recall in the history of the country – 143 million pounds of recalled beef – just last week. It's getting to the point when Americans can no longer assume that the food on their table is safe.

That there are 76 million food borne illnesses in this country each year is unacceptable. It demonstrates that there are real gaps in our food safety system – a system which doesn't come close to reflecting the technological advancements in the wealthiest and most powerful nation on earth. As a mother and grandmother, I shouldn't have to worry about whether I am serving my family contaminated food.

But then videos of downed cows being forced onto the killing floor of Hallmark/Westland Meat Packing facility are released, and I can't help but

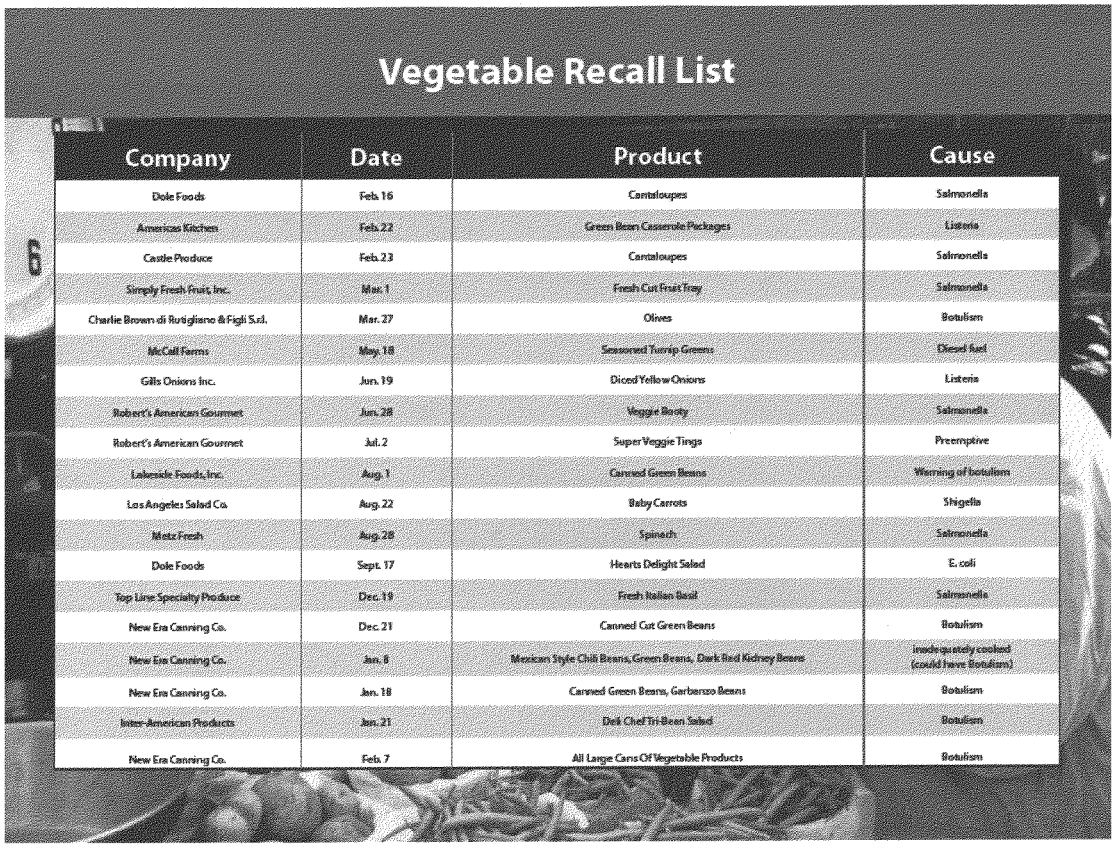
worry. It scares me to think that had the Humane Society not had a worker go undercover and pose as a Hallmark/Westland employee, this practice may have never seen the light of day. 53 million pounds of the meat that was recalled was going to be sent to our nation's schools and to nutrition programs for the poor and elderly – in other words, those populations with the weakest immune systems, who are most susceptible to food borne illnesses.

I am especially pleased to see Dr. Greger from the Humane Society here today. Dr. Greger, I am very grateful to your organization for doing the work that they do to protect the public health – I only wish I could say the same about the USDA, and about the companies whose only responsibility to the public is to follow the law and keep them safe. The USDA finally got it right when it shut down the Hallmark/Westland plant – and I am glad to see that a company which so flagrantly violated the law and betrayed the public trust is probably going out of business as a result of this horrific scandal. But I ask again: why does it take the Humane Society to do the job that the companies and the government should be doing?

So I am very curious how the representatives from the companies that manufactured the variety of contaminated food which has brought us all here today will explain the holes in their food safety systems. You all have the responsibility to put the public health first, and that this Committee has documented dozens of examples in which you have failed to do so, and that in 2008 we need to call you before Congress to explain these matters, frankly appalls me.

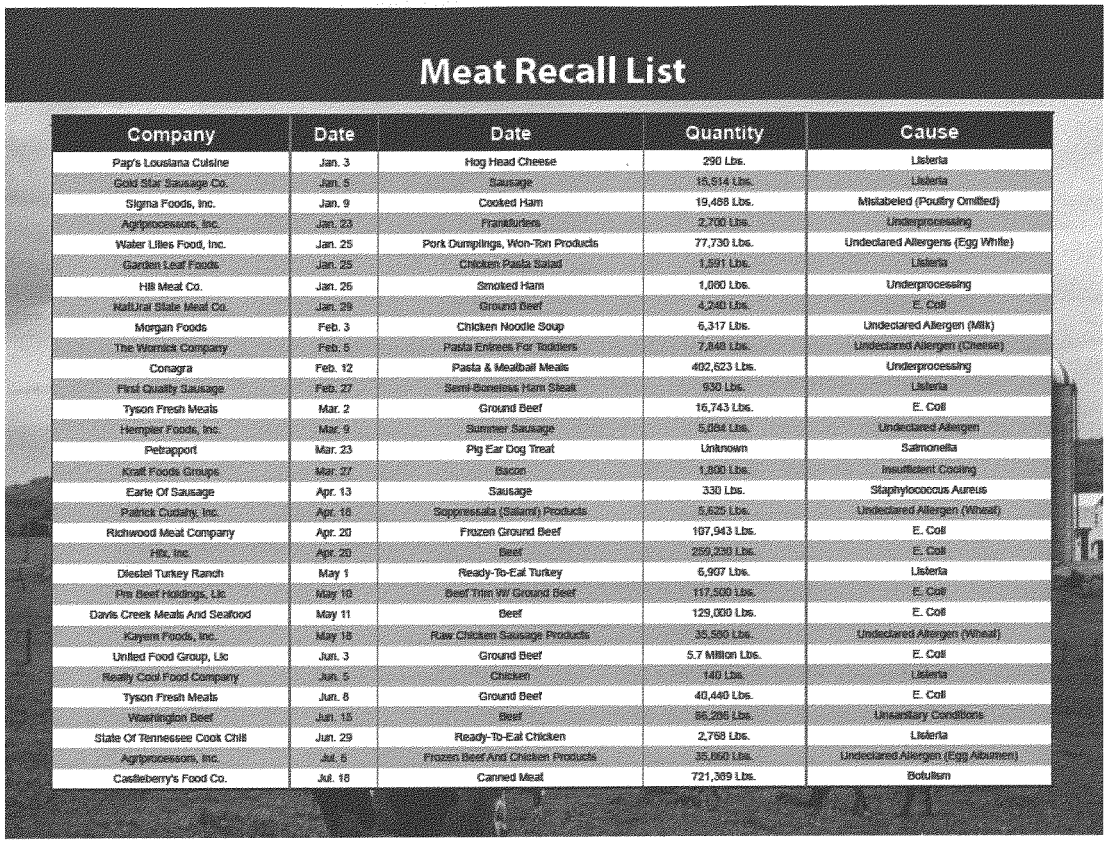
Mr. Chairman, we all deserve to know that when we go home tonight the salad that we make won't poison us, and we need answers. I thank you again for convening this hearing today, and I yield back the balance of my time.

Company	Date	Food	Quantity	Cause	Origin
Ikea	May 14	Marinated Herring		Glass	Sweden
Hong Chang Corporation	May 23	Monkfish		Tetrodotoxin	China
Everlasting Distributors, Inc.	Aug.13	Frozen Smoked Mackerel		Botulism	Phillipines
Acme Smoked Fish Corporation	Aug. 14	Smoked Salmon	246 Lbs.	Listeria	Chile Farm
Jensen's Old Fashioned Smokehouse Inc.	Sept. 7	Smoked Salmon Spread	936 Tubs	Listeria	Alaska, Washington
House Of Thaller	Oct. 29	Smoked Salmon Dip	529 Lbs.	Listeria	United States
Royal Seafood Baza, Inc.	Dec. 19	Dried Roach Fish		Botulism	Latvia
Seoul Shik Poom, Inc.	Jan. 23	Yellow Croaker		Botulism	
Choyce Products	Feb. 9	Frozen Yellowfin Tuna	5,452 Lbs.	Salmonella	

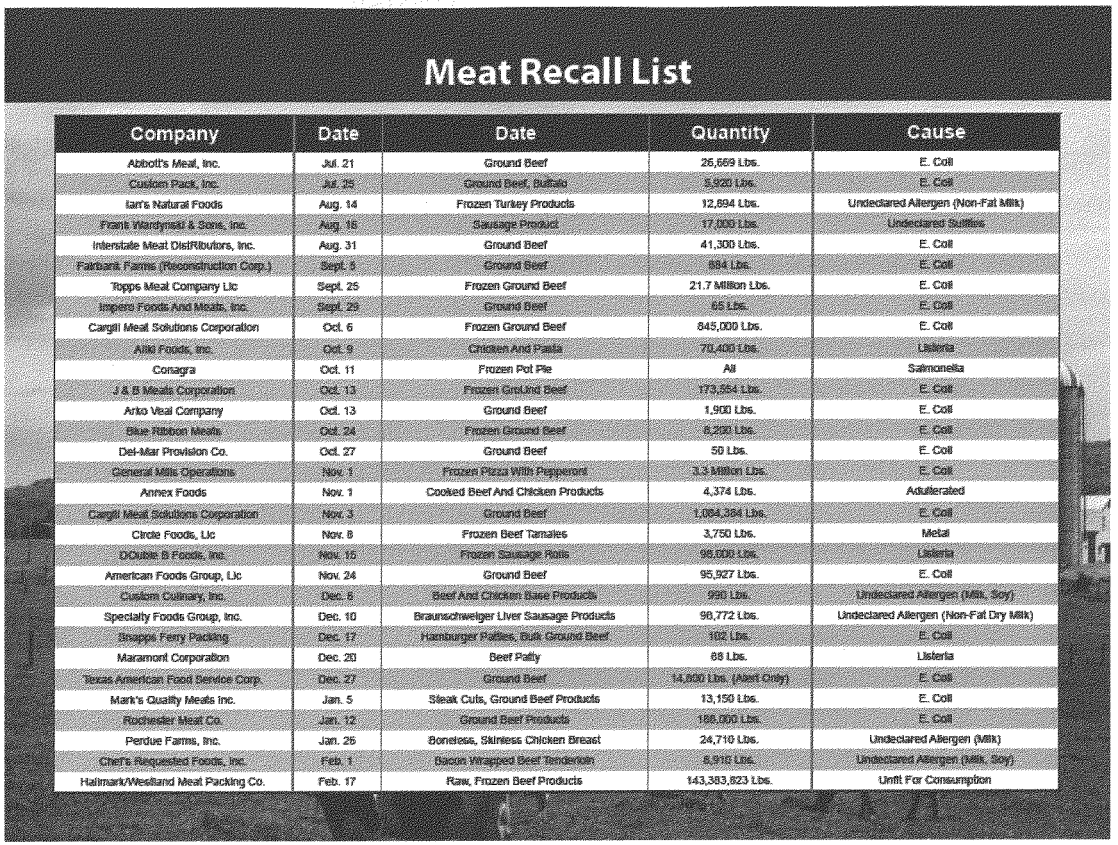


Vegetable Recall List

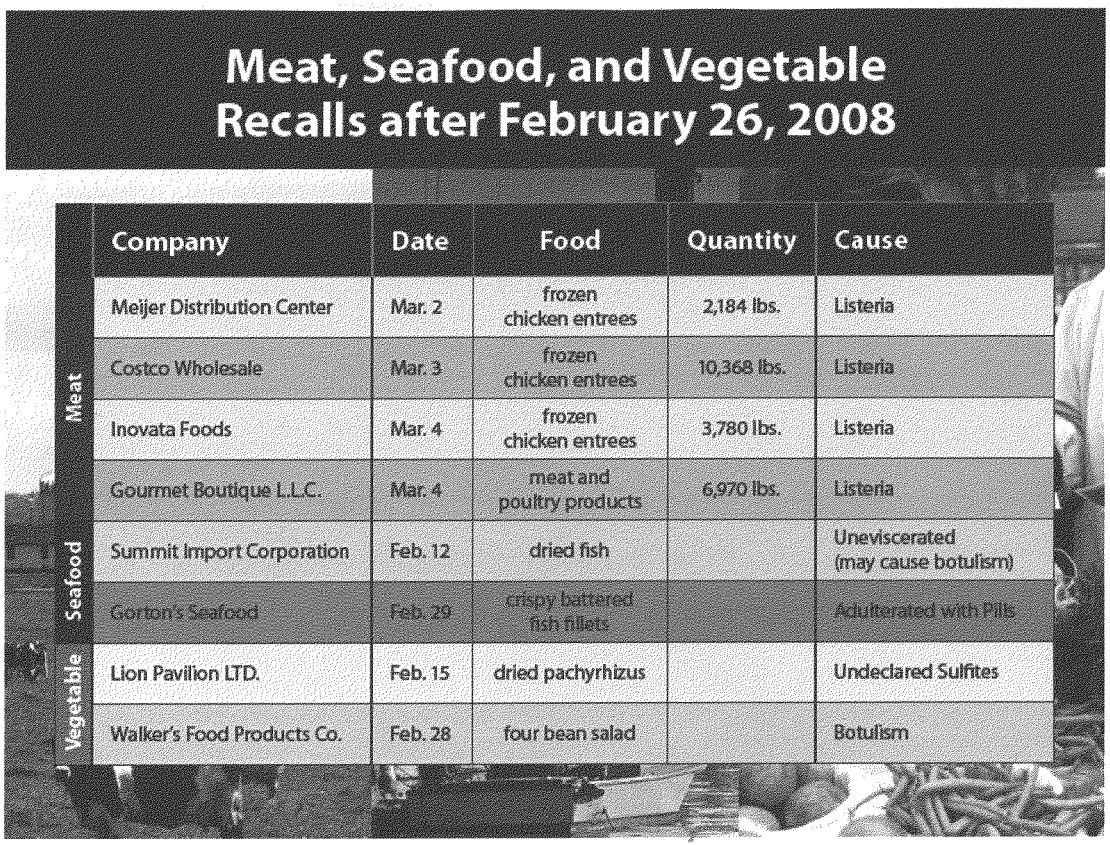
Company	Date	Product	Cause
Dole Foods	Feb. 16	Cantaloupes	Salmonella
Americas Kitchen	Feb. 22	Green Bean Casserole Packages	Listeria
Castle Produce	Feb. 23	Cantaloupes	Salmonella
Simply Fresh Fruit, Inc.	Mar. 1	Fresh Cut Fruit Tray	Salmonella
Charlie Brown di Rutigliano & Figli S.r.l.	Mar. 27	Olives	Botulism
McCall Farms	May. 18	Seasoned Turnip Greens	Diesel fuel
Gills Onions Inc.	Jun. 19	Diced Yellow Onions	Listeria
Robert's American Gourmet	Jun. 28	Veggie Booty	Salmonella
Robert's American Gourmet	Jul. 2	Super Veggie Tings	Preemptive
Lakeside Foods, Inc.	Aug. 1	Canned Green Beans	Warning of botulism
Los Angeles Salad Co.	Aug. 22	Baby Carrots	Shigella
Metz Fresh	Aug. 28	Spinach	Salmonella
Dole Foods	Sept. 17	Hearts Delight Salad	E. coli
Top Line Specialty Produce	Dec. 19	Fresh Italian Basil	Salmonella
New Era Canning Co.	Dec. 21	Canned Cut Green Beans	Botulism
New Era Canning Co.	Jan. 8	Mexican Style Chili Beans, Green Beans, Dark Red Kidney Beans	inadequately cooked (could have Botulism)
New Era Canning Co.	Jan. 18	Canned Green Beans, Garbanzo Beans	Botulism
Inter-American Products	Jan. 21	Deli Chef Tri-Bean Salad	Botulism
New Era Canning Co.	Feb. 7	All Large Cans Of Vegetable Products	Botulism



Company	Date	Date	Quantity	Cause
Pap's Louisiana Cuisine	Jan. 3	Hog Head Cheese	290 Lbs.	Listeria
Gold Star Sausage Co.	Jan. 5	Sausage	15,514 Lbs.	Listeria
Sigma Foods, Inc.	Jan. 9	Cooked Ham	19,488 Lbs.	Mislabeled (Poultry Omitted)
Agriprocessors, Inc.	Jan. 23	Frankfurters	2,700 Lbs.	Underprocessing
Water Lilies Food, Inc.	Jan. 25	Pork Dumplings, Won-Ton Products	77,730 Lbs.	Undeclared Allergens (Egg White)
Garden Leaf Foods	Jan. 25	Chicken Pasta Salad	1,591 Lbs.	Listeria
Hill Meat Co.	Jan. 26	Smoked Ham	1,080 Lbs.	Underprocessing
National State Meat Co.	Jan. 29	Ground Beef	4,240 Lbs.	E. Coli
Morgan Foods	Feb. 3	Chicken Noodle Soup	6,317 Lbs.	Undeclared Allergen (Milk)
The Wornick Company	Feb. 5	Pasta Entrees For Toddlers	7,848 Lbs.	Undeclared Allergen (Cheese)
Conagra	Feb. 12	Pasta & Meatball Meals	402,623 Lbs.	Underprocessing
First Quality Sausage	Feb. 27	Semi-Boneless Ham Steak	930 Lbs.	Listeria
Tyson Fresh Meats	Mar. 2	Ground Beef	16,743 Lbs.	E. Coli
Hempler Foods, Inc.	Mar. 9	Summer Sausage	5,004 Lbs.	Undeclared Allergen
Petrapport	Mar. 23	Pig Ear Dog Treat	Unknown	Salmonella
Kraft Foods Groups	Mar. 27	Bacon	1,800 Lbs.	Insufficient Cooking
Earle Of Sausage	Apr. 13	Sausage	330 Lbs.	Staphylococcus Aureus
Patrick Cudahy, Inc.	Apr. 18	Soppressata (Salami) Products	5,625 Lbs.	Undeclared Allergen (Wheat)
Richwood Meat Company	Apr. 20	Frozen Ground Beef	107,943 Lbs.	E. Coli
Hfx, Inc.	Apr. 20	Beef	259,230 Lbs.	E. Coli
Diestel Turkey Ranch	May 1	Ready-To-Eat Turkey	6,907 Lbs.	Listeria
Pre Beef Holdings, Llc	May 10	Beef Trim W/ Ground Beef	117,500 Lbs.	E. Coli
Davis Creek Meats And Seafood	May 11	Beef	129,000 Lbs.	E. Coli
Kayem Foods, Inc.	May 18	Raw Chicken Sausage Products	35,580 Lbs.	Undeclared Allergen (Wheat)
Unified Food Group, Llc	Jun. 3	Ground Beef	5.7 Million Lbs.	E. Coli
Really Cool Food Company	Jun. 5	Chicken	140 Lbs.	Listeria
Tyson Fresh Meats	Jun. 8	Ground Beef	40,440 Lbs.	E. Coli
Washington Beef	Jun. 15	Beef	86,296 Lbs.	Unsanitary Conditions
State Of Tennessee Cook Chill	Jun. 29	Ready-To-Eat Chicken	2,768 Lbs.	Listeria
Agriprocessors, Inc.	Jul. 6	Frozen Beef And Chicken Products	35,660 Lbs.	Undeclared Allergen (Egg Albumen)
Castleberry's Food Co.	Jul. 18	Canned Meat	721,369 Lbs.	Botulism



Company	Date	Date	Quantity	Cause
Abbott's Meat, Inc.	Jul. 21	Ground Beef	26,669 Lbs.	E. Coli
Custom Pack, Inc.	Jul. 25	Ground Beef, Buffalo	5,920 Lbs.	E. Coli
Ian's Natural Foods	Aug. 14	Frozen Turkey Products	12,894 Lbs.	Undeclared Allergen (Non-Fat Milk)
Frank Wardynski & Sons, Inc.	Aug. 16	Sausage Product	17,000 Lbs.	Undeclared Sulfites
Interstate Meat Distributors, Inc.	Aug. 31	Ground Beef	41,300 Lbs.	E. Coli
Fairbank Farms (Reconstruction Corp.)	Sept. 5	Ground Beef	894 Lbs.	E. Coli
Topps Meat Company Llc	Sept. 25	Frozen Ground Beef	21.7 Million Lbs.	E. Coli
Impero Foods And Meats, Inc.	Sept. 29	Ground Beef	65 Lbs.	E. Coli
Cargill Meat Solutions Corporation	Oct. 6	Frozen Ground Beef	845,000 Lbs.	E. Coli
Aiki Foods, Inc.	Oct. 9	Chicken And Pasta	70,400 Lbs.	Listeria
Conagra	Oct. 11	Frozen Pot Pie	All	Salmonella
J & B Meats Corporation	Oct. 13	Frozen GroUnd Beef	173,554 Lbs.	E. Coli
Arko Veal Company	Oct. 13	Ground Beef	1,900 Lbs.	E. Coli
Blue Ribbon Meats	Oct. 24	Frozen Ground Beef	8,200 Lbs.	E. Coli
Del-Mar Provision Co.	Oct. 27	Ground Beef	50 Lbs.	E. Coli
General Mills Operations	Nov. 1	Frozen Pizza With Pepperoni	3.3 Million Lbs.	E. Coli
Annex Foods	Nov. 1	Cooked Beef And Chicken Products	4,374 Lbs.	Adulterated
Cargill Meat Solutions Corporation	Nov. 3	Ground Beef	1,064,384 Lbs.	E. Coli
Circle Foods, Llc	Nov. 8	Frozen Beef Tamales	3,750 Lbs.	Metal
DOutside B Foods, Inc.	Nov. 15	Frozen Sausage Rolls	98,000 Lbs.	Listeria
American Foods Group, Llc	Nov. 24	Ground Beef	95,927 Lbs.	E. Coli
Custom Culinary, Inc.	Dec. 6	Beef And Chicken Base Products	990 Lbs.	Undeclared Allergen (Milk, Soy)
Specialty Foods Group, Inc.	Dec. 10	Braunschweiger Liver Sausage Products	98,772 Lbs.	Undeclared Allergen (Non-Fat Dry Milk)
Shapps Ferry Packing	Dec. 17	Hamburger Patties, Bulk Ground Beef	102 Lbs.	E. Coli
Maramont Corporation	Dec. 20	Beef Patty	68 Lbs.	Listeria
Texas American Food Service Corp.	Dec. 27	Ground Beef	14,800 Lbs. (Alert Only)	E. Coli
Mark's Quality Meats Inc.	Jan. 5	Steak Cuts, Ground Beef Products	13,150 Lbs.	E. Coli
Rochester Meat Co.	Jan. 12	Ground Beef Products	165,000 Lbs.	E. Coli
Perdue Farms, Inc.	Jan. 26	Boneless, Skinless Chicken Breast	24,710 Lbs.	Undeclared Allergen (Milk)
Chef's Requested Foods, Inc.	Feb. 1	Bacon Wrapped Beef Tenderloin	6,910 Lbs.	Undeclared Allergen (Milk, Soy)
Hallmark/Westland Meat Packing Co.	Feb. 17	Raw, Frozen Beef Products	143,383,823 Lbs.	Unfit For Consumption


Meat, Seafood, and Vegetable Recalls after February 26, 2008
Meat
Seafood
Vegetable
Company
Date
Food
Quantity
Cause
Meijer Distribution Center
Mar. 2
frozen chicken entrees
2,184 lbs.
Listeria
Costco Wholesale
Mar. 3
frozen chicken entrees
10,368 lbs.
Listeria
Inovata Foods
Mar. 4
frozen chicken entrees
3,780 lbs.
Listeria
Gourmet Boutique L.L.C.
Mar. 4
meat and poultry products
6,970 lbs.
Listeria
Summit Import Corporation
Feb. 12
dried fish
Uneviscerated (may cause botulism)
Gorton's Seafood
Feb. 29
crispy battered fish fillets
Adulterated with Pills
Lion Pavilion LTD.
Feb. 15
dried pachyrhizus
Undeclared Sulfites
Walker's Food Products Co.
Feb. 28
four bean salad
Botulism

School Districts Given Recalled Meat

MICHIGAN

Grand Rapids School District **(10 tons)**
Ann Arbor School District **(200 lbs.)**
Detroit Public Schools **(150 cases)**
Traverse City Area School District **(1,500 – 2,000 lbs.)**
Carrollton Public School District **(40 lbs.)**
Saginaw Township Community School District **(1/2 ton)**
Boyne City Public Schools **(80 lbs.)**
Charlevoix Public Schools **(300 – 400 lbs.)**
East Jordan School District **(100 – 150 lbs.)**
Petoskey School District **(117 lbs.)**
Marquette Area School District **(small quantity)**
Negaunee School District **(6 cases)**
Escanaba School District **(120 lbs beef, 10 cases patties)**
Pellston School District **(100 lbs.)**
Littlefield Public Schools (ordered but never received)
Lansing School District
St. Johns School District
Cheboygan Area School Districts

ILLINOIS

Quincy Public School District **(8,000 lbs.)**
Macomb School District
Camp Point Central School District
Jacksonville School District
Pleasant Hill School District

TEXAS

Fort Worth School District **(158,000 lbs.)**
Keller School District **(6,3000 lbs.)**
Houston Independent School District **(1,400 cases)**
Bonham Independent School District **(18 cases)**
Beaumont Independent School District **(137 boxes)**
Martin Independent School District **(200 lbs.)**
Socorro Independent School District **(300 cases)**
Sam Rayburn Independent School District **(1 case)**
Mansfield School District
Rusk Independent School District
Azle School District

TEXAS (cont.)

Azle School District
Castleberry School District
New Summerfield School District
Alto School District
Grapevine-Colleyville School District
Birdville School District
Pasadena School District
Clear Creek School District
Jacksonville Independent School District
Waco Independent School District

PENNSYLVANIA

Souderton Area Schools District
Towanda Area School District
Scranton School District
Pittsburg Public Schools
Northeast School District

PENNSYLVANIA (cont.)

Laurel Highlands School District
Allentown School District
Bangor Area School District
Bellefonte Area School District
Bloomsburg Area School District
Blue Mountain School District
Danville Area School District
Dunmore School District
Greater Nanticoke School District
Hanover Area School District
Hazleton Area School District
La Salle Academy
Lehigh Career and Technical Institute
Lehighton Area School District
Line Mountain School District
Mahanoy Area School District
Mountain View School District
Nazareth Area School District
Northampton Area School District
Northern Lehigh School District

PENNSYLVANIA (cont.)

Northern Tioga School District
Old Forge School District
Pocono Mountain School District
Riverside School District
Saucon Valley School District
Sayre Area School District
Schuylkill Valley School District
Shenandoah Valley School District
St. Columbia School
St. Sebastian School
St. Vincent School
St. John the Baptist School
Stroudsburg Area School District
Sun Area Vo-Tech
Tri-Valley School District
Tunkhannock Area School District
Valley View School District
Warrior Run School District
West Side Area Vo-Tech

PENNSYLVANIA (cont.)

Western Wayne School District
Whitehall-Coplay School District
Wilkes-Barre Area School District
Wyoming Area School District
Wyoming Valley West School District

CALIFORNIA

Chino Valley Unified School District
Los Angeles Unified School District

#	Description	Date
	ConAgra - Peanut Butter Documents	
1	FDA News Release, subject: "FDA Warns Consumers Not to Eat Certain Jars of Peter Pan Peanut Butter and Great Value Peanut Butter."	02/14/2007
2	Establishment Inspection Report, ConAgra Grocery Products	03/02/2007
3	Associated Press article by Josh Funk, subject: "Peanut Butter Contamination Pinned on Moisture."	04/05/2007
4	Foodproductiondaily.com article by George Reynolds, subject: "ConAgra to Reopen Renovated Plant."	07/08/2007
5	Newsinferno.com article, subject: "Peter Pan Peanut Butter Salmonella Outbreak Marks Year Anniversary."	02/15/2008
	ConAgra - Pot Pie Documents	
6	USDA Food Safety Inspection Service (FSIS) Recall Release, subject: "Missouri Firm Recalls Frozen Pot Pie Products for Possible Salmonella Contamination."	10/11/2007
7	Associated Press article by Josh Funk, subject: "ConAgra Asks Stores to Quit Selling Pies."	10/11/2007
8	USDA FSIS Notice of Intended Enforcement to ConAgra Foods	10/23/2007
9	CDC Investigation of Outbreak of Human Infections Caused by Salmonella I 4, (5), 12:i:-	10/29/2007
10	Newsinferno.com article, subject: "ConAgra Banquet Pot Pie Salmonella Victims Now Number 272, CDC Says."	10/31/2007
	Castleberry's Food Company Documents	
11	FDA Recall Press Release, subject: "Castleberry's Announces Voluntary Recall of Chili Products."	07/18/2007
12	USDA FSIS Recall Release, subject: "Georgia Firm Recalls Canned Meat Products That May Contain Clostridium botulinum."	07/19/2007
13	Associated Press article, subject: "Castleberrry's Shuts Georgia Plant as Part of botulism Probe."	07/19/2007
14	FDA Recall Press Release, subject: "Castleberry's Expands Voluntary Recall of Hot Dog Chili Sauce and Canned Meat Products."	07/21/2007
15	FDA News Release, subject: "FDA Expands its Nationwide Warning About the Risk of Botulism Poisoning From Certain Castleberry's Food Products and Dog Food."	07/21/2007
16	USDA FSIS Recall Release, subject: "Georgia Firm Expands Recall of Canned Meat Products That May Contain Clostridium botulinum."	08/02/2007
17	Establishment Inspection Report, Castleberry's Food Company	08/10/2007
18	CDC announcement, subject "Botulism Associated with Canned Chili Sauce, July - August 2007."	08/24/2007

	Dole Documents	
19	FDA Recall Press Release, subject: "Dole Fresh Vegetables Announces Voluntary Recall of 'Dole Hearts Delight' Packaged Salads."	09/17/2007
20	SFGate.com article by George Raine, et al, subject: "E. coli Scare Prompts Recall of Bagged Lettuce by Dole."	09/18/2007
	Hallmark/Westland Meat Packing Documents	
21	Washington Post article by Rick Weiss, subject: "Inspectors Verify Abuse of Cows in California."	02/07/2007
22	The Press-Enterprise article by Janet Zimmerman, subject: "Criminal Investigators Look at Slaughterhouse."	02/08/2008
23	USDA FSIS Recall Release, subject: "California Firm Recalls Beef Products Derived from Non-Ambulatory Cattle Without the Benefit of Proper Inspection."	02/17/2008
24	The Wall Street Journal article by David Kesmodel, et al, subject: "Beef Industry Presses for Reduced Recall."	02/22/2008
	New Era Canning Documents	
25	FDA Recall Press Release, subject: "New Era Canning Company Recalls Canned GFS Fancy Blue Lake Cut Green Beans Because of Possible Health Risk."	12/21/2007
26	FDA Recall Press Release, subject: "New Era Canning Company Announces New Recall of Certain Lots of Mexican-style Chili Beans, Green Beans and Dark Red Kidney Beans Because of Possible Health Risk."	01/08/2008
27	FDA Recall Press Release, subject: "New Era Canning Company Announces New Nationwide Recall of Green Beans and Garbanzo Beans in #10 Cans (6 to 7 pound cans)."	01/18/2008
28	FDA News Release, subject: "New Era Canning Expands Nationwide Recall: Risk of botulism from Additional Canned Vegetable Products."	02/07/2008
29	FDA Recall Press Release, subject: "New Era Canning Company Announces New Nationwide Recall of Vegetable Products in #10 Cans (6 to 7 pound cans)."	02/07/2008
30	Newsinferno.com article, subject: "New Era Canning Issues Vegetable Recall Amid Botulism Fears."	02/08/2008
	Seafood Documents	
31	FDA Import Alert, subject: "Detention Without Physical Examinationof Aquacultured Catfish, Basa, Shrimp, Dace, and Eel Products from the People's Republic of China Due to the Presence of New Animal Drugs and/or Unsafe Food Additives."	08/03/2007
32	Associated Press article by Justin Pritchard, subject: "FDA Investigates Import Seafood Claims."	08/09/2007

33	The New York Times article by David Barboza, subject: "In China, Farming Fish in Toxic Waters."	12/15/2007
	Additional Documents	
34	FDA Statement on Foodbourne E. coli O157:h7 Outbreak in Spinach	09/15/2006
35	FDA Recall Press Release, subject: "California Department of Public Health Warns Consumers Not to Eat Fresh Ginger from China."	07/29/2007
36	FDA Recall Press Release, subject: "Metz Fresh Announces Voluntary Recall of Spinach."	08/28/2007
37	California Department of Health Care Services, Food and Drug Branch List of Environmental Investigation Reports	
38	FDA Guidance for Industry report, subject: "Guide to Minimize Food Safety Hazards for Fresh-cut Fruits and Vegetables; Availability."	02/22/2008
39	Associated Press article by Ivan Moreno, subject: "Beef Industry, Animal Rights Group Duel."	
40	The Wall Street Journal Article by David Kesmodel and Jane Zhang, subject: "Meatpacker in Cow-Abuse Scandal May Shut as Congress Turns Up Heat."	02/25/2008
41	FDA Inspection Form 483: New Era Canning Company	11/26/2007
42	The Humane Society issue summary, subject: "Downers, Human Health Hazard and USDA Policy."	01/30/2008

FDA News

FOR IMMEDIATE RELEASE
P07-21
February 14, 2007

Media Inquiries:
301-827-6242
Consumer Inquiries:
1-888-SAFEFOOD

FDA Warns Consumers Not to Eat Certain Jars of Peter Pan Peanut Butter and Great Value Peanut Butter

Product May be Contaminated With Salmonella

The Food and Drug Administration (FDA) is warning consumers not to eat certain jars of Peter Pan peanut butter or Great Value peanut butter due to risk of contamination with *Salmonella* Tennessee (a bacterium that causes foodborne illness). The affected jars of Peter Pan and Great Value peanut butter have a product code located on the lid of the jar that begins with the number "2111." Both the Peter Pan and Great Value brands are manufactured in a single facility in Georgia by ConAgra. Great Value peanut butter made by other manufacturers is not affected.

If consumers have any of this Peter Pan or Great Value brand peanut butter in their home that has been purchased since May 2006, they should discard it.

Symptoms of foodborne illness caused by Salmonella include fever, diarrhea and abdominal cramps. In persons with poor underlying health or weakened immune systems, Salmonella can invade the bloodstream and cause life-threatening infections. Individuals who have recently eaten Peter Pan and Great Value brand peanut butter beginning with product code 2111 and have experienced any of these symptoms should contact their doctor or health care provider immediately. Any such illnesses should be reported to state or local health authorities.

FDA's warning is based on a just-completed epidemiological study by the Centers for Disease Control and Prevention (CDC), the states and local health agencies, which links 288 cases of foodborne illness in 39 states to consumption of varying types of Peter Pan peanut butter. This report was provided to FDA on February 13.

The outbreak appears to be ongoing and the first consumer may have become ill in August 2006. The cause of foodborne illnesses can be difficult to identify. As a result of extensive epidemiological testing and recent case control studies, CDC was recently able to identify Peter Pan peanut butter as the likely cause of illness. Great Value brand peanut butter beginning with product code 2111 is manufactured in the same plant as Peter Pan peanut butter and, thus, is believed to be at similar risk of contamination.

ConAgra is recalling all Peter Pan and Great Value peanut butter beginning with product code 2111 that already was distributed. The company also is destroying all affected products in their possession. The company will cease production until the exact cause of contamination can be identified and eliminated. ConAgra will advise consumers to destroy any Peter Pan and Great Value brand peanut butter beginning with product code 2111 in their possession. To assist in this endeavor, FDA has sent investigators to ConAgra's processing plant in Sylvester, Georgia where the products are made to review records, collect product samples and conduct tests for *Salmonella* Tennessee.

FDA will provide regular updates as more information becomes available.

Consumers who have questions should contact ConAgra at 866-344-6970.

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Photos: Peter Pan and Great Value Peanut Butter

Questions and Answers: Peter Pan & Great Value Peanut Butter Salmonella Outbreak and Product Recall

FDA's Pilot Program to Better Educate Consumers about Recalled Food Products

RSS Feed for FDA News Releases [what's this?]

Establishment Inspection Report	FEI:	**1038538**
ConAgra Grocery Products	EI Start:	02/14/2007
Sylvester, GA 31791-0585	EI End:	03/02/2007

SUMMARY

The current inspection of this peanut butter manufacturer was conducted as per a directed assignment from ATL-DO to conduct an inspection of this firm prompted by the notification from FDA's Office of Emergency Operations of a suspected food-borne illness outbreak of *Salmonella Tennessee*. Extensive epidemiological testing and case control studies collected by the CDC identified peanut butter manufactured by ConAgra Grocery Products in Sylvester, GA as the likely source of the ongoing outbreak. According to the CDC data, this is a multi-state outbreak with onset dates ranging from August 1, 2006 to January 21, 2007. See ATTACHMENT A for detailed background information for this outbreak.

Investigators were instructed to start the follow-up inspection of ConAgra Foods in Sylvester, GA as soon as possible on 2/14/07. Based on case control studies by the CDC, lot codes from containers of peanut butter found in the homes of patient's with confirmed *Salmonella Tennessee* were provided to FDA. Instructions issued to the FDA Investigators included collecting environmental swabs throughout the plant, collecting finished product and raw ingredient samples, reviewing records pertaining to quality control and production (initially concentrating on suspect lot code dates provided and the onset time frame of the outbreak).

This firm operates as the only manufacturer of Peter Pan Peanut Butter Products and one of several producers of Great Value Peanut Butter products (Wal-Mart/Sam's Club brand). The focus of the current inspection was to determine if and what products manufactured at this firm were contaminated with *Salmonella* and any possible sources of product contamination in the firm. At 6:30 p.m. on 2/14/07, the firm voluntarily shut down operations; therefore, the inspection of the firm's equipment and production lines in operation was limited. Other areas covered during the inspection included in-house testing results and procedures, consumer complaints, maintenance and installation of equipment, cleaning and sanitizing procedures, raw materials/ingredients, product inventory and distribution, record review, and sample collections. Numerous samples, consisting of finished product, raw ingredients, and environmental swabs, were collected during the inspection, and shipped to the Southeast Regional Lab for *Salmonella* analysis. DOC sample #409799 was collected to document the interstate commerce of 2800 cases of Peter Pan Products shipped from ConAgra Grocery Products, Sylvester, GA to FTW Dry IMC, Fort Worth, TX on 2/14/07. Descriptions of samples collected are included in the "Samples Collected" section at the end of this report. Collection Reports for these samples are attached to the report.

ADMINISTRATIVE DATA

Inspected firm:	ConAgra Grocery Products
Location:	101 S Seabrook Dr
	P.O. Box 585
	Sylvester, GA 31791-0585
Phone:	229-776-8811

Establishment Inspection Report	FEI:	**1038538**
ConAgra Grocery Products	EI Start:	02/14/2007
Sylvester, GA 31791-0585	EI End:	03/02/2007

FAX:

Mailing address:	101 S Seabrook Dr/P.B. 585 Sylvester, GA 31791
Dates of inspection:	2/14/2007, 2/15/2007, 2/16/2007, 2/17/2007, 2/18/2007, 2/19/2007, 2/20/2007, 2/21/2007, 2/22/2007, 2/23/2007, 2/26/2007, 2/27/2007, 2/28/2007, 3/1/2007, 3/2/2007
Days in the facility:	15
Participants:	Janet B Gray, Investigator Jackie M. Douglas, Investigator

HISTORY

This firm operates as a division of ConAgra Foods, Inc. under the Canning Platform. The corporate office for ConAgra is located at 1 ConAgra Drive, Omaha, NE 68102 and the home office for the Canning Platform is located in Naperville, IL. The division office is located in Irvine, CA. Mr. Gary Rodkin was identified as the CEO of ConAgra Foods, Omaha, NE. See EXHIBIT # 1 for the organizational chart for ConAgra Foods. Mr. Gary Rodkin is the CEO and most responsible individual for ConAgra Foods Inc. Individuals responsible for operations and QA at this location were identified as Earl G. Ehret, Plant Manager, and A. Joseph (Joey) Kimbrell, Quality Control Manager. Numerous members of management from this location and other divisions were present during the inspection. Each name and title of everyone involved are listed under the "Persons Interviewed and Individual Responsibility" heading of this report.

The previous inspection of this firm on 2/23-24/05 was conducted in response to several consumer complaints including an anonymous complaint with specific allegations of an episode of positive findings of *Salmonella* in peanut butter in October of 2004. The complainant also alleged that the firm had an insufficient response to the microbial problems relating to inadequate cleaning of new equipment, insect activity in plant, water leaking onto product, and inability to track some product. Management verbally reported that each day's production is tested in-house for *Salmonella* and coliforms prior to the release of the product. The firm acknowledged that there was some production in October of 2004 that did not meet product specifications and was put on a "Micro" hold, and was subsequently destroyed. Management refused to provide details to include the exact cause of the hold and the type/amount of product involved. The firm did provide a review of micro testing results on 2 dates in October that were reported to be 2 dates on which new votators (heat exchangers) were placed on the lines after having been cleaned and sanitized. Tests on both dates were "negative" for *Salmonella* and coliforms.

The previous inspection revealed areas on two packaging lines where filled containers of peanut butter were not completely covered, and both were corrected during the inspection. The Investigator did not find any leaking water lines or overhead condensation, etc. leaking into any exposed product, either on packaging lines or in the raw and roasted peanut handling areas. No evidence of insects or activity were observed around the product elevators and elevator boots, bins, aspiration lines, foreign material chutes, destoners, blanchers, or electronic sorters. Management expressed concern over the complaints and reported that some of the allegations are time-related to a recent employee dismissal, and that recent plant mechanization resulting in a number of employees losing their jobs has resulted in some employee resentment. A FDA 483, Inspectional Observations, was not issued, but several concerns were verbally discussed with management. A finished product sample of peanut butter produced during the inspection on 2/24/05 was collected and submitted to SRL for microbial analysis. Lab analysis revealed that the sample was negative. The firm has no regulatory history.

Approximately 1 hour into the current inspection, Robert Rish, District Supervisor and Bill Jones, Sanitarian/Inspector with the Georgia Department of Agriculture requested a joint inspection of the plant. The request was granted and GDA inspectors joined the inspection. Mr. Rish was present during the inspection from 2/14-21/07. Inspector Jones accompanied the Investigators every day of the inspection, except for the closing on 3/2/07. The GDA collected finished product samples in conjunction with the FDA Investigators.

INTERSTATE COMMERCE

The firm's finished products are routinely shipped to various distribution centers located throughout the country, see EXHIBIT # 2 for a copy of the distribution/inventory centers used by the firm. Additionally, the firm ships some product directly to Wal-Mart or Sam's stores. See EXHIBIT # 3 for the product inventory by location as of 2/17/07 for products shipped from this plant. EXHIBIT # 4 is a list of the product codes or SKU numbers used by the firm to identify product types and sizes.

Documentary Sample # 409799 documents the interstate commerce of 2800 cases of Peter Pan Products shipped from ConAgra Grocery Products, Sylvester, GA to FTW Dry IMC, Fort Worth, TX on 2/14/07. The Collection Report, attached to this report, includes the FDA-463a, Affidavit, read and signed by the Plant Manager, and the Bill of Lading for the above shipment.

Sample # 409792, collected on 2/21/07 consisted of 15/18 oz. jars of Great Value Reduced Fat Peanut Butter Spread collected from the firm's warehouse inventory. Included with the collection report is Shipping Ticket, PPSID # 39270, dated 2/6/07, from Wright Enrichment, Inc. in Crowley, LA, to ConAgra Grocery Products in Sylvester, GA documenting the IS movement of 40/22.679 kg. boxes of Smart Choice Vitamin/Mineral Blend IVO28, lot # 10701123, used as an ingredient in the manufacture of Great Value Reduced Fat Peanut Butter Spread. The FDA-463a also documents the use of this ingredient in the firm's operations and the IS of this ingredient.

The collection report and corresponding records for the above samples are attached to this report.

Establishment Inspection Report	FEI:	**1038538**
ConAgra Grocery Products	EI Start:	02/14/2007
Sylvester, GA 31791-0585	EI End:	03/02/2007

JURISDICTION

The firm manufactures a variety of peanut butter products packaged under the Peter Pan label and Great Value label, which include the following:

Peter Pan Creamy (18, 22, 28, 40, and 56 oz., 6 lb, 500 lb.)
Peter Pan Crunchy (18, 22, 28, and 40 oz.)
Peter Pan Creamy Honey Roast Peanut Butter (18 and 28 oz.)
Peter Pan Crunchy Honey Roast Peanut Butter (18 oz.)
Peter Pan Creamy No Sugar Added Peanut Spread (18 oz.)
Peter Pan Creamy Whipped Peanut Butter (14 oz.)
Peter Pan Creamy Plus Peanut Butter with Vitamins and Minerals (17.6 oz.)
Peter Pan Creamy Reduced Fat Peanut Butter Spread (18 and 28 oz.)
Peter Pan Crunchy Reduced Fat Peanut Butter Spread (18 oz.)
Great Value Creamy Peanut Butter (18, 28, and 40 oz.)
Great Value Crunchy Peanut Butter (18, 28 and 40 oz.)
Great Value Reduce Fat Peanut Butter Spread (18 oz.)

See EXHIBIT # 5 for the product labels provided by the firm. [Note: the firm no longer packages peanut butter in 12 oz. containers (label on page 1 of Exhibit # 5), and no products have been produced under the Arabic label since 2002 (label on page 5 of Exhibit # 5); however, these labels were also provided.]

The majority of the peanut butter products are packaged in plastic jars with plastic screw cap lids. The 6 lb. containers of peanut butter are packaged in foil lined cardboard composite barrels, with metal lids. The label for this product is included with EXHIBIT # 5. The bulk peanut butter is packaged in 55 gallon cardboard fiber drums with a plastic interior lining with a metal sealing ring, see EXHIBIT # 6 for a copy of a drum label and EXHIBIT # 7 for the Letter of Inspection from the drum supplier. The bulk drums of peanut butter are shipped internally to two locations: ConAgra portion pack plant located in Placentia, CA, packaged under the Peter Pan label; and the ConAgra Humboldt, TN plant distributing ice cream topping under the J. Hungerford Smith label.

According to the firm, peanut butter products produced at this plant are only packaged under Peter Pan and Great Value labels. No soy or other legume butters are produced at this firm. The firm indicated that approximately 6-7 years ago they had produced peanut butter under the private label Panner. When they stopped producing this product, Tara Foods (peanut butter manufacturer located in Albany, GA) took over the production of this product. Also, at one time the firm had packaged peanut butter for small "mom and pop" type stores, under Newton Farms label (this was so far back that no one at the firm knew exactly how long ago this was). Management informed us that at this time, no other labels are used by this firm and the Peter Pan jar shapes are proprietary.

According to the firm, only domestic peanuts, primarily from Georgia, are used in the production of their peanut butter products (i.e. Golden Peanut Co. in Ashburn, GA and Dawson, GA; McCleskey Mills in Smithville, GA; Birdsong Peanut Co. in Sylvester, GA, Donalsonville, GA, and Colquitt, GA). The firm normally receives raw peanuts in bulk tanker trucks, but occasionally the firm receives raw peanuts in 2200 lb capacity bulk cardboard boxes or totes from blanching facilities, such as American Blanching in Fitzgerald, GA and Universal Blanchers in Sylvester, GA. Each lot of raw peanuts is accompanied with a USDA certificate of analysis (COA), which is reviewed prior to releasing the peanuts for processing.

Additional raw ingredients used for the manufacture of peanut butter products at this plant include peanut oil, salt, corn starch, sugar, stabilizer, honey, molasses, corn syrup solids, vitamins, soy protein concentrate, and Splenda. Photographed labels of raw ingredients on hand at the plant were provided by the firm (EXHIBIT # 8). The firm does not test incoming raw materials except for peanuts which are checked for moisture and aflatoxin levels. Ingredients are purchased from approved suppliers and each lot comes with a COA. Microbial specifications are included on the COA's provided with the sugar, soy protein concentrate and Splenda, see EXHIBIT # 9.

Packaging supplies used by the firm include caps, jars, trays, cans, labels, etc. The source and list of raw ingredients and materials used for the firm's manufacturing operations is included as EXHIBIT # 10. Materials are visually examined upon receipt for damage and defects. As jars come into the warehouse, they are checked for foreign material, correct size, moisture, damage and defects. The firm does not receive a COA or conduct lab testing on jars and caps. The investigator's inquired if they had experienced any problems or had any recalls with their ingredients or packaging materials within the last year. Management said that the only problems they had concerned some defected jars that were rejected upon receipt and a few pallets of jars that were rejected because some evidence of moisture was detected. The Quality Control Manager provided us with the Shipping Ticket and Hold notice for the shipment of 2 pallets of "wet" jars shipped to the firm on March of 2006. The jars were rejected and returned to the supplier, see EXHIBIT # 11. Additionally, management stated that approximately 2 years ago the firm had received a lot of raw peanuts that "failed" their aflatest. The lot was delivered to the firm and unloaded into the storage bins, but they were notified of the aflatoxin analysis before the lot was used. Reportedly, Federal and State officials were notified of the incident. According to management, the firm has not received any recalls from their suppliers for the past 2 years.

Oil or lubricants are used on various equipment throughout the process flow. See EXIHIBIT # 12 for a list of the lubricants, venders, and where used. There is no water added as an ingredient for the products manufactured at this plant. The firm has city water and it is used only for clean out of place (COP) equipment and mopping floors.

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITY

The inspection was initiated on 2/14/07. Credentials were presented to and the FDA-482, Notice of Inspection, (and "Resources for FDA Regulated Businesses" document) was issued to Mr. Earl G. Ehret, Plant Manager. Present also at this time were the following members of management: Chris

C. Horan, Director of Enterprise Quality; A. Joseph (Joey) Kimbrell, Quality Control Manager; Erdal Tuncan, Director of Microbiology; and Tom Cherven, Enterprise Sanitation Manager.

FDA correspondence should be sent to Don Jones, Sr. Director of Quality and Food Safety, Omaha, NE. The corporate office gave the final authorization allowing us to review or receive a copy of records requested during the inspection. Delays experienced during the inspection concerning access to records were due to the fact that the firm was required to make a copy of each record provided to the FDA and all of these records had to be passed through the corporate office before being released to the Investigators. Also, some information requested by the FDA was not part of the firm's standard procedures or records, and had to be compiled by various members of management.

Ms. Chris C. Horan, Director of Enterprise Quality, stated that she works in the Irvine, CA office, and she reports to Don Jones in the corporate office in Omaha, NE. She reported that she is the Quality Director over the canning and grocery division of ConAgra. During the inspection, Ms. Horan acted as the liaison between the Sylvester plant and the corporate office. She was responsible for sending all record requests through the corporate office for permission to provide documents to the Investigators. Ms. Horan was present for each discussion during the inspection, except for the closing on 3/2/07. She provided intermittent accompaniment during sample collections and plant walk-through. The majority of the records given to FDA were provided by Ms. Horan.

Mr. Earl G. Ehret is the Plant Manager of this facility and the most responsible individual for the day-to-day operations at this facility. Shortly after the arrival at the firm, we were informed that Mr. Ehret has been the Plant Manger for only 3 weeks. He said that his official start date at the firm was 1/15/07, and he had replaced Mr. Tom Gentle, the previous Plant Manager. Mr. Ehret told us that he would cooperate in any way that he could, but information concerning specific details of the operation and events that occurred prior to his arrival would be difficult for him to answer. Mr. Ehret provided accompaniment throughout the inspection. The FDA-482, Notice of Inspection, and FDA-484, Receipt for Samples, was issued to Mr. Ehret. In addition, he read and signed the FDA 463a, Affidavit, during the closing discussion.

Mr. A. Joseph Kimbrell, Quality Control Manager, is responsible for all quality control functions in the plant, including, cleaning and sanitation procedures and in-house tests for finished product and environmental swabs. Mr. Kimbrell provided accompaniment throughout the inspection. Mr. Kimbrell provided information pertaining to laboratory procedures, cleaning supplies, sanitation program, and methodology for in-house tests.

Thomas Gentle, former Plant Manager, joined the inspection on 2/15/07. Mr. Gentle now works in the Omaha, NE office, but he stated that the corporate office ask that he come down to the Sylvester plant to assist in the walk-through inspection of the plant since he was familiar with the equipment and operations. During the initial walk-through of the production area, Mr. Gentle described the equipment and process flow of the plant. He accompanied us each day of the inspection until his

departure on 2/20/07.

Erdal Tuncan, Director of Microbiology, Omaha, NE, provided information pertaining to in-house testing procedures, and he collected environmental swabs for the firm on 2/15/07. Mr. Tuncan was present for the inspection from 2/14-2/16/07.

LaLit Boltra, Senior Microbiologist, Omaha, NE, provided intermittent accompaniment during the inspection, and he reports to Mr. Tuncan.

Tom Cherven, Sanitation Manager Enterprise Quality, Naperville, IL, provided intermittent accompaniment during the inspection and information for sanitation policies.

Other key operations personnel at the Sylvester, GA plant included:
Dennis Yeckel, Production Manager, provided accompaniment during sample collections, and supplied information pertaining to production lines and product inventory.

Joe Malinowski, Production Supervisor, accompanied us during walk-through inspections of the plant. He provided information pertaining to the process flow, equipment functions (i.e. roaster, homogenizer, votators, and diaphragm valves).

Dave Taylor, Maintenance Supervisor, provided information pertaining to maintenance and repairs of equipment in plant, such as maintenance of closed system (Line Entry Permit) and additives for cooling towers.

Clarence Davis, 2nd Shift Production Supervisor, Chuck Hobby, Focused Improvement, and Matt Jordan, Maintenance Supervisor, accompanied us during the collection of environmental swabs and finished product sampling, and provided information pertaining to production lines, and equipment functions.

Tabitha Giddens, Cost Manager, provided assistance in record requests and provided information pertaining to the history of firm.

At the initiation of the inspection, we explained that the inspection was in response to the CDC's epidemiological findings implicating peanut butter manufactured from this firm as the source of a food borne outbreak linked to *Salmonella Tennessee*. We discussed that CDC's data covered a time period of August 2006 to December of 2006. Management told us that they were already aware of the implications, but they had just found out the previous night and they did not have any idea of the products or production dates involved. Ms. Horan stated that they had been busy reviewing records from January 2006 to the present, and they had not found any indications of problems. She commented that their ingredient suppliers had not issued any product recalls. We explained that there did not appear to be one specific product or a specific production date implicated. We told

them that we had a list provided by the CDC that identified certain products and the lot codes gathered from the open jars found in the homes of the consumers involved in the outbreak. We explained that we were given permission to share the lot codes with the firm, but any other questions concerning statistics or studies involving the outbreak should be discussed with the CDC. We reminded them to keep in mind that the codes were not all complete and might not follow their coding system exactly due to the fact that the codes were gathered by the consumers and/or state employees across the United States. The following products and lot codes are quoted directly from CDC's cluster study list provided to FDA. Note that some codes appear to be missing #'s (i.e. "211"); however, the codes were listed as such and provided to the firm as follows:

Product	Lot Code	Use By Date
Peter Pan Creamy	211163460014020	6122008
Peter Pan Creamy	211162430008340	08/2012
Peter Pan Creamy	21116248000543 B	03052008
Peter Pan Creamy	21115251000805A	03082008
Peter Pan Creamy	211427300223913	3302006
Peter Pan Creamy	211163380021598	06042008
Peter Pan Creamy	21116258002929A	312008
Peter Pan Crunchy	21116094000807A	1042007
Peter Pan Honey Roast	21162360013098	02242008
Peter Pan	2111177??7002249	2252008
Peter Pan Creamy Smart Choice	211163260022480	5222008
Great Value Crunchy	2111634100210A	672008
Great Value Crunchy	2116213000022C	02012008

From this information, Mr. Kimbrell was able to trace the production date for the suspect products, EXHIBIT # 13. We ask to review the finished product test results for these specific dates, and Ms. Horan stated that she would find out through the corporate headquarters if it would be okay for us to review the records. After some time, Ms. Horan allowed us to review the finished product test results for the suspect lots. No deficiencies were found during the review. Copies of these records were subsequently provided to the Investigators and included as EXHIBIT # 14.

The Investigators told the firm that this inspection would more than likely be extensive and that our immediate instructions were to collect environmental swabs throughout the plant. We explained that 2 microbiologist from the Southeast Regional Lab would be joining us on the following day to assist with the collection of the environmental swabs.

We told the firm that we would like to collect finished product samples, and we ask if there was a chance that they still had product in their warehouse that was produced within the same time frame as some of the suspect production dates. We were informed that they usually don't have anything

older than 10 weeks in the warehouse, but they would check their inventory. After checking the inventory we were told that the oldest product they had was 18 oz. Peter Pan Creamy produced on 11/9/06. We attempted to find product produced on or around the suspect production dates, therefore, 3 of the oldest dated products were collected on 2/14/07 from the firm's warehouse inventory.

Sample # 366079 consisting of 15/18 oz. jars of Peter Pan Creamy Peanut Butter, production date 12/07/06, were collected from the sampled lot of 2739 cases in the firm's warehouse. This product was produced for export, thus the lot code varied from the usual coding system. Each jar had a code printed in dot-matrix on the top of the lid of "PRD 11/09/06" "EXP 11/09/08 ICOMTRADE." Sample # 366080 consisting of 15/18 oz. jars of Great Value Crunchy Peanut Butter, production date 12/7/06, were collected from the sample lot of 62 cases in the firm's warehouse. Sample # 366076 consisting of 15/22 oz. jars of Peter Pan Crunchy Peanut Butter, production date 11/16/06, were collected from the sampled lot of 1673 cases in the firm's warehouse. The Collection Reports for the above samples are attached to this report. FDA-484 for the above samples was issued to Mr. Earl Ehret, Plant Manger, at the end of the day on 2/14/07.

OPERATIONS, PERSONNEL, AND EQUIPMENT
[INFORMATION IN THIS SECTION IS PROPRIETARY AND CONSIDERED A TRADE SECRET BY THE FIRM.]

The firm is currently operating 5 days per week, running 2/10 hour shifts per day. The first shift runs from 6 AM to 4 PM, and the second shift from 4 PM to 2 AM. Ms. Horan said that they had been operating with 3 shifts for the past 2 years, but approximately 2 weeks ago they changed and went back to 2 shifts. Sanitation operations are staffed 24 hours per day, with any major clean-ups performed during the down time from 2 AM to 6 AM and on weekends. The firm has 108 hourly and 20 salary employees.

Processing Flow/Equipment
[It should be noted that after the Investigators left the firm on 2/14/07, first day of inspection, the firm voluntarily shut down operations around 6:30 p.m. The first day of the inspection was spent interviewing management, discussing and requesting records, and collecting 3 finished product samples. Thus, we did not observe the production of peanut butter during the inspection.]

The manufacturing process since the last FDA inspection in February of 2005 has not changed. The production equipment and operations found at this firm are typical to the industry. See EXHIBIT # 22 for plant diagrams of the firm.

Raw peanuts are shipped to the firm in dedicated bulk tankers owned by Southern Ag. The raw peanuts are vacuumed out of the tankers and off-loaded into bulk bins for temporary holding. The bulk bins are split into quarters amounting to 12 separate bins, each with the capacity of 40,000-50,000 lbs. Each bulk bin has a ticket on the side identifying the bin #, lot # of raw peanuts (first 2

#'s of lot identify the supplier), date the lot was received, and the # of bulk delivery truck. The firm can select raw peanuts for manufacturing operations from one bin or from several bins (this would produce a co-mingled lot). This allows the firm the ability to trace a specific lot or supplier from a production date. The firm normally receives only bulk tanker trucks of peanuts that are pneumatically unloaded, but occasionally the firm receives raw peanuts in 2200 lb capacity bulk cardboard boxes from blanching facilities, such as American Blanching in Fitzgerald, GA and Universal Blanchers in Sylvester, GA. These boxes are new and are not reused by the firm to store peanuts used for human consumption. Raw peanuts from the cardboard cartons are dumped into the bulk bins.

Raw peanuts delivered to the firm are accompanied by the USDA Grade and Inspection Certificate and Aflatoxin analysis report. The raw nuts are visually inspected by the firm's QC department, and in-house samples are collected for aflatoxin (max. of 15 ppb for sub samples) and moisture content (usually about 7 %). The firm does not have a minimum or maximum limit for moisture, however, the higher the moisture the longer the peanuts would have to be roasted. According to management, the firm is currently using the 2005 crop of peanuts in their production.

From the bulk holding bins, the raw peanuts are gravity fed onto a horizontal conveyer which carries the raw nuts to the vertical bucket conveyor that extends through the concrete block wall separating the raw receiving and pre-clean room. Raw peanuts enter into the pre-cleaning room on the conveyor and are transported into the holding bin which discharges the nuts into the scalper, which mechanically removes foreign objects through vibratory screening and aspiration. Sticks and other large foreign objects vibrate across the top screen of the equipment and are separated from the peanuts which fall through the top screen onto a second screen. The raw peanuts that move across the second screen are discharged into a bucket conveyor which leads into the holding bin supplying raw peanuts to 2 destoners (LMC Gravity Separators), which removes stones, metal objects, etc. Small peanut pieces and broken peanut kernels, etc. that fall through the second screen are also conveyed to the LMC Gravity Separators. All sizes of peanuts from the primary gravity separator are combined and enter a horizontal bucket conveyor which is discharged into the secondary LMC gravity separator. From this gravity separator the peanuts are conveyed to a bucket conveyor which empties into a screw auger that extends through the concrete block wall separating the roasting room from the pre-cleaning room. Cleaned peanuts are transferred into a holding bin, where peanuts are gravity fed onto the rotating stainless steel belt of the Procter-Schwartz Roaster.

According to the firm, the peanuts are roasted at an air temperature of 300°F for a minimum of 5 minutes. The peanuts are layered 4 5/8 inches in depth on a 10 foot belt that passes through 8 heating zones and back down through 4 cooling zones. The dwell time is monitored by belt speed, which is measured in Hertz (feet/minute). Maximum belt speed of the roaster is 50 hertz, equal to 5.7 feet per minute/ 2.7 minutes per zone. The firm runs the belt speed at 44-44.5 Hertz, which is equivalent to 3.1 minutes per zone, for a total of 16.2 minutes in the heating zones.

Roaster Zones

Product enters at ambient temperature. H= heating zone C= cooling zone

H1	H2	H3	H4	H5	H6	H7	H8	C1	C2	C3	C4
212-215°F	>300°F	>300°F	>300°F	>300°F	>300°F	>300°F	340°F				100-120°F
3.1 min	3.1 min	3.1 min	3.1 min	3.1 min	3.1 min	3.1 min	3.1 min	3.1 min	3.1 min	3.1 min	3.1 min

When product enters the cooling zones, this stops the cooking process so the product is not overcooked. Filtered air, generated from a chilled water system blown through a squirrel cage fan, is blown onto the peanuts for a target temperature of 100°F. The chilled water system is like compressed air coming from a chilled source, but there is no water directly on the product. It should be noted that the area near the exit end of the roaster is not covered. Peanuts fall off the roaster belt at 100-120°F onto the vibratory belt.

See EXHIBIT # 23 for a copy of the firm's HACCP plan for the peanut butter products, and EXHIBIT # 24 for the firm's HACCP plan for the Smart Choice or Reduced Fat products. The cook time is longer than the CCP of 5 minutes. Ms. Horan stated that they cook longer to achieve the desired color of roasted peanuts. The entire run from end to end is approximately 36 minutes total dwell time in roaster, (includes heating and cooling zones). Original information provided by Mr. Gentle on 2/15/07, was that the peanuts were roasted at 350°F for 5 minutes. Note that the temperature monitored in the roaster is air temperature, not actual temperature of the product. The peanuts are not probed during roasting, thus the firm can not determine the actual temperature of the peanuts during the roasting stage. Ms. Horan stated that they were not aware of any studies conducted that would validate the temperature of the peanuts while being roasted. The times and temperatures within the roaster are monitored in a control room where the information is electronically charted. The roaster time and temperature charts were not reviewed during the inspection. However, the firm's management was questioned regarding any roaster malfunctions and we were told during the inspection they were aware of none.

The roasted peanuts are transferred from the roaster onto a horizontal vibratory conveyor that moves the peanuts to a vertical bucket conveyor, where the peanuts are discharged to the upstairs holding bins, each having a 45,000 lb. capacity. From the holding bins, roasted peanuts are fed into the split nut blanchers, where the nuts are mechanically split and skins are removed from the peanuts and aspirated from the process flow. The nuts are then conveyed on a horizontal bucket conveyor to the electronic sorting system (8-channel ESM Satake Scan Masters) which rejects off-colored nuts, foreign material, etc. from the product flow. Rejects go through the color sorters 2 more times, and any product rejected 3 times is discarded. Aspirated peanut skins and rejects are used in animal feeds. Blanched peanuts passing through the color sorters are transferred to a horizontal vibratory conveyor, which transports the nuts to a vertical bucket elevator, which conveys blanched roasted

peanuts to the holding bins on the mezzanine. It should be noted that the firm has open-topped bins in which roasted peanuts are held.

At this point, roasted and cleaned peanuts in the holding bins are gravity fed into an auger that empties into the Bauer Mill, the primary grinding mills. Once the peanuts enter the Bauer mill the manufacturing operation is considered to be a closed system. During the grinding steps, some heat is generated in the grinding mills with the product reaching approximately 135° F. Peanut oil is added to the roasted blanched peanuts during the primary/coarse grinding stage. To make crunchy peanut butter, roasted peanuts are diverted in the product flow prior to the primary mill and go through the Urschel chopper where the peanuts are chopped and passed through two Sweco screens to grade the nuts for suitable sizes. Chopped peanuts are then transferred to a holding bin and stored until added to the process flow prior to filling for the crunchy style peanut butter products. Coarsely ground peanuts from the primary grinding mills are gravity fed into an enclosed micro-motion mixing auger that discharges into the formulation tanks (stainless steel kettles) located on the first floor. At this stage, ingredients such as sugar, starch, salt, and stabilizer are added to the product. The product temperature drops to approximately 128°F at this stage because of the addition of the dry ingredients. Ingredients such as honey and molasses are added at this stage for the Honey Roasted Products. The weight of ingredients added at the screw auger are controlled and monitored by a computer.

The firm has established a separate system for products containing soy, such as the Reduced Fat or Smart Choice products. The addition of ingredients and the mixing of these products are conducted in the Readco Mixing room. This area is equipped with hoppers and a Readco mill, which blends the ingredients. After the primary grind, the product goes to the formulation tank where the stabilizer is added , then to the mixing tank in the Readco Mixing room where soy protein and corn syrup solids are added to the product. The product is then discharges to the Urschel mill for the final grind.

The peanut butter is then conveyed back to the Urschel Mill for a final grind to achieve a creamy texture. During the final grind process, the friction from the mixing of the ingredients causes the temperature of the product to increase to 145-150° F. Next, the peanut butter is pumped to the de-aeration tank for removal of air. During the de-aeration process the temperature of the product decreases to about 132° F. Cooled peanut butter is pumped through an in-line filter located between the pre-cooling section and homogenizing section. Temperatures generated by the homogenization step are approximately 165° F. Peanut butter is then conveyed from the homogenizers by a stainless steel header to the votators. At this time, the peanut butter passes through votators or heat exchangers to cool down the product. The cool down temperature after passing through the votators for creamy and crunchy peanut butter is within +/- 2° of 92° F before passing to the filling machines. The Honey Roasted peanut butter is +/- 2° of 95° F, and the Smart Choice/Reduced Fat products is 100°F. The cooling media in the votators is Freon for all products, with the exception of the smart choice/reduced fat products which are cooled by chilled water in the votators.

Creamy peanut butter is conveyed from the votators to the fillers. For crunchy peanut butter, chopped peanuts temporarily stored in the holding bin are discharged to the weight feeders and added to the peanut butter flow at the mixing tanks prior to filling. The firm's whipped peanut butter product is manufactured as described above, but nitrogen is mixed with the product prior to the filling stage.

The filling room has 4 filling or packaging lines (5 including the filling line for the 55 gallon fiber drums), designated as lines A, B, C, and D. All filling lines are fed from one main line coming from the run tanks, and the lines are split off just before going to the fillers. According to management, crunchy peanut butter products can only be run on lines A and B, and creamy peanut butter products can be run on lines A, B, C and D. Line A is used to fill 12 and 18 oz. jars; line B is used to fill 22, 28 and 40 oz. jars; line C is used to fill 12, 18, 22, 28, and 56 oz. jars; and line D is used to fill 6 lb. cans of creamy and 18 and 28 oz. jars of smart choice/reduced fat products.

Empty jars are inverted and blown out with compressed air jets prior to filling. The jars are the conveyed to the fillers. Peanut butter is mechanically filled at about 89 to 90° F on rotating fillers which enter the jars and fill from the bottom to the top. The filled jars exit the fillers and are conveyed through the metal detector, then nitrogen is injected into the head space of each jar prior to the plastic screw cap being applied to each jar. An induction seal is applied to the cap by passing the closed jars under a heat sealing machine, which seals the metal foil liner on the cap to the mouth of the jar. Sealed jars are passed through another metal detector to make sure a foil label is applied. Sealed jars are passed under an ink-jet printer which prints the manufacturing code on the top of each screw cap. Next the jars are conveyed to the labeling machine. Six lb. composite cans are coded on the side of the can approximately 1" from the bottom of the can. Labeled jars are then mechanically packaged into cardboard shipping cases, which are shrink wrapped in clear plastic and case coded. The finished products are initially stored in the firm's warehouse, until ready for distribution. The warehouse is also used for storage of packaging materials (jars, caps, cases, etc.).

Cleaning/Sanitation Procedures

There are no clean-in-place (CIP) procedures in this plant. According to Mr. Kimbrell, there is no water used in the plant, with the exception of a small amount of water mixed with Clorox used for mopping the floors in the production areas. Any wet cleaning or "clean out of place" (COP) is performed in the wet wash room and any equipment wet cleaned is dismantled and removed to that area for the cleaning. Equipment or utensils such as star-wheels, indexers, screws, screens, buckets, tools, cappers, and filters are taken off of the lines and taken for cleaning in the wet wash room. The equipment removed from the production line is hosed down with water, scrubbed by brushes with GPC cleaner, allowed to air dry, wiped down with alcohol, wrapped in plastic, and taken back to the production area. For example, the in-line filters or strainer baskets located between the pre-cooling section and homogenizing section are COP. These filters are cleaned on a production needs basis not just for routine sanitizing. When filters are replaced there is a cleaned and sanitized filter wrapped in plastic and ready for the replacement. Reportedly, any new product contact equipment installed is cleaned and sanitized with alcohol at installation, and microbial swabs are taken.

The buckets or totes used on the production line on the clean side of the plant are removed and cleaned each weekend in the wet wash room. The buckets used on the raw side of the operations are only cleaned 2 times a month, but these buckets are blown down every weekend. Both sets of buckets undergo the same cleaning procedure.

The manufacturing equipment in the closed system, primary grinders to the fillers, are not broken down and entered unless mechanical problems develop. When this happens, the section of the system requiring maintenance is entered and repaired. The equipment is sanitized by wiping down with alcohol and reassembling. No water is used for this procedure.

The roaster is cleaned weekly by a foaming cleanser that is sprayed onto the roaster as the belt is rotated around the frame. The roaster is equipped with a rinse bar at the discharge end, located between the belts, of the roaster that is used to rinse off the foam from the roaster belt. Water from the rinse bar is sprayed onto the belt for approximately 2 rotations (usually 1 ½ - 2 hours). Next, the roaster is run for approximately 2 cycles to dry. The rinse bar is not included in the monthly environmental swabs.

Cleaning and sanitizing supplies used by the firm include:

Lappet E3 Plus (Best Sanitizers, Inc.) is a hand sanitizer used throughout the plant.

Eco-Wipe FCS (Ecolab) used only in the firm's lab to wipe counter tops; not used in the plant.

Quorum Clear (Ecolab) is a liquid sanitizer used on equipment and utensils for COP; after rinsing equipment is wiped down with alcohol. Used weekly.

Quorum Green (Ecolab) is a chlorine based sanitizer used in the wash room and employee entrance for cleaning floors. Used weekly.

Questar GPC (Ecolab) is a cleaner used primarily as a degreaser on frames and machinery. Cleaner is sprayed on and wiped down with alcohol. Used daily.

Quorum Amber (Ecolab) is a self-foaming cleaner used in the Readco Room on walls and machinery frames. Used weekly.

Medallion SS (Ecolab) cleaner used to polish the outside of tanks. Used weekly.

Pathways Drain Sanitizer (Ecolab) used as a time released solid-detergent cleaner for the wash room drain. Replaced weekly.

Wash and Walk (Ecolab) used to clean floors and high oil areas; allowed to air dry. Used weekly.

Hot Foam (Astro Products) is sprayed on the roaster as the belt is rotated around the frame. Used weekly.

See EXHIBIT # 15 for product description and specifications for the above cleaners and sanitizers.

In-house testing procedures

We ask the firm about their in-house testing and sampling procedures. Mr. Kimbrell reported the firm performs micro testing, which consists of total coliform count and *Salmonella,* on finished product, and the product is not released until tested and found within specifications. Mr. Kimbrell stated that he was responsible for the QA testing and that their sampling of finished product for *Salmonella* was run on GeneQuence Salmonella (24-hour enrichment). Mr. Tuncan stated that GeneQuence is a DNA hybridization test that has been approved by the AOAC. We ask the firm if we could have a copy of the manufacturer's insert for the GeneQuence. On 2/16/07, we received a partial package insert (EXHIBIT # 16), therefore, once again we ask for the complete package insert. On 2/17/07, we were given the complete package insert, see EXHIBIT # 17.

Samples of sealed jars are collected across the shift's production and tests are performed on composites from those samples. Sample size for the finished product is 1 container per line / per hour / per shift of the product being produced. Containers taken from the same production line are composited. Sample analysis size ranges from 25 grams to 250 grams. 25 grams of product is removed from each jar. Thus, if 5 jars are sampled from a production run then the composite sample size is 125 grams. For this composite a 1:10 dilution with an enrichment broth is made, so 1250 ml. of broth would be added to the composite. This composite is incubated for 24 hr at 36° C. After incubation, 10 ml of the pre-enrichment culture is removed and added to 10 ml of double strength Gram Negative Broth and incubated 6 hours at 36° C. After this incubation, 1 ml. is removed from the enrichment culture and run on GeneQuence Salmonella. [According to Mr. Kimbrell, the product and the enrichment broth are mixed by shaking/swirling. Investigator Gray inquired if he ever used a blender to mix the peanut butter and broth so that the mixture was consistently combined, making sure that all portions of the composite were penetrated. Mr. Kimbrell stated that he had not experienced any problems with this because the peanut butter always seemed to dissolve or separate after shaking. I stated that I was curious about the method because the SRL used blenders when conducting Salmonella analysis to make sure that large thick composite of peanut butter were uniformly mixed. It should be noted that no laboratory procedures and/or rapid test methods were observed during the inspection.] See EXHIBIT # 18 and 18B for a copy of the 2005 Finished Product Analysis results, and EXHIBIT # 19 for a copy of the 2006 Finished Product Analysis results. No deficiencies were found during the review of these records.

After a quick review of the finished product analytical results, we ask Mr. Kimbrell about the positive and negative controls used during the testing procedures with the GeneQuence. He said that he used the controls that were provided with the kit. Investigator Gray then asks if he ever spiked product (peanut butter) with *Salmonella* to confirm that *Salmonella* in peanut butter could be picked up on the GeneQuence. Ms. Horan immediately, spoke up and said that they do not allow viable *Salmonella* in the firm.

Mr. Kimbrell reported that the firm has a monthly swabbing program that includes swabbing 20 different areas in the plant (equipment, overhead walk-way, floors, etc.). See EXHBIT # 20 for a copy of the Environmental Swab test results for 2005 and EXHIBIT # 21 for the test results for 2006. No deficiencies were found during the review of these records. The locations in the plant that are swabbed monthly are listed on the records. Mr. Kimbrell said that a different spot in each of the 20 locations is swabbed monthly.

He said he has 4 lab techs that work for him that usually collect the swabs, and he is responsible for running the tests in the lab. The swabs are also run on the GeneQuence Salmonella (24 hour enrichment). The swabs are aseptically collected and each swab is placed in 10 ml of enrichment broth and incubated for 24 hours at 36° C. After incubation, 1 ml of the culture is removed and added to 10 ml of double strength Gram Negative Broth and incubated for 6 hours at 36° C. After this incubation, 1 ml. from the enrichment culture is removed and run on GeneQuence Salmonella.

Mr. Tuncan reported that the firm collects swabs each week from equipment and food contact surfaces that are run on an ATP (Adenosine Triphosphate) bioluminescence test, which rapidly detects a potential source of microbial contamination. The relative light produced is directly related to the number microorganisms present. The more relative light unit (RLU) detected, the more ATP produced by microbes. This procedure tells you if the area is clean, but it is not specific for detecting organisms. According to Mr. Tuncan, if the ATP shows luminescence, then the area is recleaned and sanitized. No records pertaining to this procedure were reviewed during the inspection.

Total coliform count is also identified in the finished product and by environmental swabs and recorded on the same analysis report as the Salmonella tests. The total coliform count in a sample is determined by the 3M Petrifilm Coliform Count method, which is recorded as the number of Colony Forming Units (cfu) per gram of product. The results give the firm an idea of the general hygiene and sanitation control during the production of peanut butter products.

On the first day of the inspection, we had asked if the firm had encountered any positive *Salmonella* test results in its environmental swabs or finished product testing, and we had been told no by Mr. Kimbrell, the Quality Control Manager. Mr. Kimbrell said they had not had a positive test for *Salmonella* since he has been employed at the firm and he started working there in 2002.

Other finished product tests include aflatoxin test, head space, insect fragments/rodent hair, defects, particle test, burst test on seal, hourly and 24 hours consistency test, color (roasted peanuts and finished product), torque on cap, net weight . On crunchy products the drain weight is checked. The firm does not check water activity of the finished product.

MANUFACTURING CODES

The lot codes for each product are inked in black dot-matrix on the jar lids of each product, with the exception of the product packaged in the 6 lb. composite containers which bears the code on the lower side of each container. The lot codes consists of the plant identification #, year, julian date, 00 space filler, military time, and product line.

For example: "21115251000805A"

2111 =is the Sylvester plant number
5 =is the year 2005

251= is the julian date
00 = used as space filler, always "00"
0805= is the 4 digit military time of production
A =is the production line (A,B,C,D)

[Note that at one time the firm's plant identifier character began with the letter "S", however, the firm changed to the "2111" around 2004.] There is a slight variation in how the "use by date" is declared on Great Value products. The firm's "Use by Date" is 18 months from the production date. Code breakdown is the same for both Peter Pan and Great Value and is located on the lid. Products exported by ConAgra have a variation in the product code and the labels are specific for name of product not the country the product is shipped to. Products are exported to multiple countries; the international distribution list was copied to a CD and sent to ATL-DO. There are 5 export code variations, see EXHIBIT # 25 .

MAINTENANCE/REPAIR ISSUES/CONCERNS

During the inspection we asked the firm if they had experienced any maintenance or repair issues concerning equipment that was directly involved in the production steps. We were told that they have not had any serious problems that they could think of at the time. We discussed the replacement of the roaster, and asked if there had been any problems with the old roaster. Management said that they have had no problems with the roaster other than just routine maintenance. According to Tom Gentle, the roaster belt has been replaced several times, and after each replacement, the roaster is cleaned according to the weekly cleaning procedures as described above in the "cleaning/sanitizing procedures" section of this report. Also, the firm quickly added that they were intending to replace the old roaster before all of this happened, mainly because it was old and had been installed in the plant by the original owners, Seabrook, back in 1975. Reportedly, the firm started construction work in October of 2006 for the placement of the new roaster. The new roaster is manufactured by Aeroglide, and the firm anticipates that the new roaster will be installed and operable by May 1, 2007. The firm stated that the new roaster will have 20 % more capacity and will produce a more efficient duel burn.

The Investigators asked the firm if there had been any changes in suppliers or ingredients within the last year that might affect their products. The firm said that they had changed the supplier of the nitrogen in July of 2006 from Praxair to Air Liquide. According to management, this was a coordinated effort between the two companies because the actual nitrogen tank, which is located outside, was changed. The exchange was completed on a Saturday during down-time at the firm. The tank was emptied completely, the valve was turned off, and then the tank was exchanged. The exchange was completed within one day. The tank is not new, but reconditioned. A carbon steel line delivers nitrogen into the plant via pipes with the pressure of 85 lbs. psi. The nitrogen is withdrawn as a gas by passing the liquid nitrogen through its own vapor pressure. The nitrogen is distributed to various points in the plant where used (i.e. head space on bulk process tanks and storage tanks, head space on product containers). Management stated that the valve was turned off during the exchange;

however, the tanks could have been changed with out the valve being shut. The firm is not aware of any instances where water could have entered the system.

Two 200 horse power air compressors supply air to the dryers, where the air is filtered. Three automatic air surge tanks, each with moisture drains, provide bursts of compressed air to the filling lines. The B-line is equipped with it own independent air-flow system of de-ionized air from a local blower that is monitored and filtered at this location. The firm said that the surge tanks have not been changed; however, they reported that they did have a problem with a compressor on the air dryer and it was replaced in October of 2006. They stated that this was refrigerated air and prior to the surge tank, so there was not a problem. Monthly environmental swabs do not include surge tanks or filter drains.

We discussed if there had been any leaks or if there was the possibility of water coming into contact with the smart choice/reduced fat product that passes through the chilled water votators. The firm explained that this is a closed system, where the peanut butter flows through a cylindrical tube surrounded by a larger cylinder where the chilled water is circulated through. The interior piping of the votators is a food contact surface, with the pipe passing through a cooling medium to effect the temperature change. According to Mr. Dave Taylor, in a closed system such as this, there will naturally be a loss of water by evaporation, and there is no way to tell the difference between a leak and evaporation. However, the temperature of the product is observed throughout the votator by a temperature probe that is monitored in the control room. If a 1° change is detected it would indicate a leak. The chilled water temperature fluctuates between 39-43°F. The firm said that the single circulation for all votators is about 9000 lbs./hr. The firm said that pressure differential of the water and the product would also signify a leak. Management indicated that the pressure on the product side is higher (60-80 lbs. psi) than the pressure on the water side (35-40 lbs psi); therefore, if there was a leak you would have product in the water, not vice versa. Included in that explanation was a comment that the cooling tower water is checked for clarity on a regular schedule and finding cloudy or milky water would indicate a leak or a problem.

According to the firm, their bulk water tank, which is equipped with a float bulb, is filled from a municipal water source. When the water level drops, the float valve would be triggered to add water. Water is treated between the bulk tank and votators cooling system. The firm reported that they have had no breakdowns on the chiller system. Mr. Taylor stated that the water is treated with an algaecide produced by Ecolab. The firm provided us with records from Ecolab about treatment materials added to cooling water in the chilled water system that is pumped through the votators/heat exchangers on the peanut butter line that uses chilled water. See EXHIBIT # 26 for a copy of these records.

We inquired then as to how this equipment is cleaned. Mr. Dave Taylor reported that the votators are dismantled, cleaned and sanitized, and that documentation would record this procedure. Investigator Douglas then asked if the equipment was swabbed or checked in some manner to validate the effectiveness of the cleaning, and if the firm had records to verify the cleaning and validation.

Reportedly, the firm maintains a line entry program for documenting any equipment on the closed production line that is dismantled and removed, cleaned and sanitized, and placed back onto the line. On 2/20/07, we ask to review these records. On 3/2/07, Mr. Ehret provided the Line Entry Permits from January of 2006 to the present date to Investigator Gray for a review. [Note that we were not given a copy of these records, they were available for review only.] The Line Entry Permits are completed when maintenance has to go into the "closed" portion of the product line, basically the part from the grinding mills to the fillers. These records document information such as the service performed, GMP's and safety regulations checks, who performs work, date, and the sanitizer used. The records reviewed consisted only of maintenance work involving the replacement of valves, balls, seats, and pistons adaptors for homogenizers and standard maintenance of the urschel mill. I asked Mr. Ehret if it was typical to replace parts on the homogenizers every 2-3 months, and he informed me that this was a common procedure conducted for the maintenance of the homogenizers.

We also asked for records that would document the cooling tower checks or any maintenance work in 2006. We were told that these checks should be part of the preventative maintenance records. We were not provided any other records pertaining to the cooling tower checks during the inspection. On 3/2/07 the last day of the inspection, Mr. Ehret informed Investigator Gray that Ms. Horan was gathering this information; however, she was currently traveling back to CA and he was not aware of any information she might have obtained at this time. He stated that he would let Ms. Horan know that we continued to ask for this information, and he would tell her to contact Investigator Gray about any records or information she had found. As of 3/29/07, Ms. Horan has not contacted the Investigators with this information.

We inquired if the firm was aware of any diaphragm valves used in any of the processing equipment. We explained that we were trying to determine if these valves could be a potential source of product residue. The firm said that they have diaphragm valves in many of the vessels in the closed portion of the system and that the diaphragm valves operate the sensors that monitor the product level in the vessels. The diaphragm is used as a level transmitter that works from the pressure of the product, and indicates the tank level to a computer. Mr. Malinowski explained that all diaphragm valves used in the firm's systems are stainless steel and every tank that has a sensor has a diaphragm valve. The valve has a stainless steel plate (large flat disk 4" in diameter) with a soft center that moves in and out. Product is pushed against the diaphragm to give a signal of the tank level. Product touches only the flat disk, and all elements that come into contact with the product are made of stainless steel. No rubber diaphragms are used, so no abrasions or scratches would be created on the diaphragms. Management stated that they were not sure how many diaphragm valves they had in their equipment or the manufacturer of these valves, but they would work on compiling a list for us. The firm does not routinely keep such a record; therefore, it took several days to collect this data requested. On 3/2/07, Mr. Ehret provided me with a list of the location and manufacturer of diaphragm pressure gauges (valves) in the plant. [Note that this record was provided only for review, no copies were provided to the Investigators.]. According to the document:

-- 56 diaphragm valves are located on equipment in the upstairs area (grinding/formulation/ingredient addition), the valves are manufactured by Bourdon Haenni/Weskler;

--28 diaphragm valves are located in the downstairs tank room, the valves are manufactured by Bourdon Haenni/Weskler;

--34 diaphragm valves are located in the Electronis (feeds the ABB), the valves are manufactured by RoseMount;

--6 diaphragm valves are located in the homogenizers, the valves are manufactured by Neodyn;

--8 diaphragm valves are located in the Urschel Mills, the valves are manufactured by Neodyn.

During the inspection, we asked management if they were aware of any employee illnesses that might have contributed to product contamination. The firm presented us with a 1 ½" thick binder filled with calls made by employees for being tardy, sick, attending funerals, etc. We explained that we only wanted to know if they maintained employee health records that might identify a specific time period or employee that could have contributed to a microbial contamination in the plant. On 2/26/07, Ms. Horan informed us that she had not actually sat down and reviewed the employee illness records. She said that as a team they would address any data that looked significant. On 2/28/2007, Mr. Ehret informed me that they had pulled the data concerning employee illnesses, and they had not found any trends or any thing that could be connected.

CONSUMER COMPLAINTS

On 2/14/07, we asked the firm if they had received any consumer complaints that might be connected to the current situation, and management replied that they were not aware of any complaints, but Ms. Horan stated that she would look into it and let us know what she found. On 2/20/07, Ms. Horan informed us that the corporate office was supposed to be printing a list of consumer complaints they had received within the past year that had similar allegations. She explained that ordinarily consumer complaints are handled by the corporate office because their product labels list the address and toll free phone # for the office in Omaha, NE for any questions or comments, thus the Sylvester plant would not be contacted directly by consumers.

At this time, information concerning a consumer complaint received in December of 2006, Reference # 051314249A, for Peter Pan Reduced Fat Creamy was inquired about. The complainant reported that her husband and two grandchildren became ill with diarrhea, vomiting, and unknown fever after eating peanut butter on 2 separate occasions. The consumer called ConAgra in December and ConAgra sent her a pre-postage paid envelope for her to send the product to them so that they could do laboratory testing on the product. The product was mailed to ConAgra on 12/12/06. Reportedly, the consumer called ConAgra several times for the test results, but they had no information to give her. We ask management if they were aware of the complaint, and Ms. Horan informed us that to the best of her knowledge no one at this plant was aware of this complaint. We gave Ms. Horan the consumer's name and the reference #, and ask if she could collect some information on the episode and give us an idea of the outcome. Later that day, Ms. Horan informed us that she had discussed the above complaint with Don Jones, Sen. Director of Food Safety and

Quality, and he said that at the time of this complaint it was not their policy to analyze opened jars of product because they didn't know if the product had in fact made the consumer sick or if the consumer had contaminated the product after it was opened. Also, we asked if they kept retain samples of product shipped to them by consumers, and she said that she would check.

On 2/21/07, management informed us that they had this particular complaint in their records and they did maintain a retain sample. Ms. Horan stated that they planned on analyzing this opened product. The results from the test were not released or discussed with the investigators. On 2/23/07, we received a list of consumer complaints (alleged illness) compiled by the corporate office for the time period of 1/1/06 to 2/14/07, see EXHIBIT # 27 . The firm was not sure if they had retained samples for any of the other consumer complaints or what, if any, follow-up was conducted. No other complaints were discussed during the inspection.

OCTOBER 2004 POSITIVE SALMONELLA RESULTS

On the first day of the inspection, we had asked if the firm had encountered any positive *Salmonella* test results in its environmental swabs or finished product testing, and we had been told no by Mr. Kimbrell, the Quality Manger. On 2/23/07, Mr. Kimbrell provided to us copies of the firm's swab testing results for 2005 and 2006. Investigator Douglas asked him if he was a microbiologist and he replied yes. Investigator Douglas then repeated to him what he had told us earlier, that he had been here since 2002, and he said yes. Mr. Kimbrell was then asked if he would remember or know of any positive test results, and he said yes. Investigator Douglas once again asked if the firm had ever had any swabs or finished product samples positive for *Salmonella*, and Mr. Kimbrell said no, but he appeared to hesitate in his answer. Investigator Douglas voiced that he detected some hesitation in his answer, and asked had there been any positive tests of anything. At this time, Ms. Horan immediately said that the firm had 2 positive *Salmonella* tests in October of 2004, but none of the product ever got out. She further explained that the firm had 2 positive *Salmonella* test results from peanut butter samples, however, the product involved was destroyed and none of it was released from the plant. She said the firm performed extensive swabbing and testing, but they were not able to identify the source.

Investigator Douglas told Ms. Horan that this sounded familiar to him in that during the February 2005 inspection he had conducted at the firm involved consumer complaints FDA had received, including an anonymous complaint indicating the firm had a "micro problem". He said that during the 2005 inspection he was told only that the firm had placed product on a micro hold and that the product was destroyed. Ms. Horan once more stated that none of the product got out.

Ms. Horan later explained that they thought that our questioning earlier in the inspection and Mr. Kimbrell's negative response to us had been in reference only to environmental swab testing. We told her that was not the case, and she said they obviously misunderstood. She said that their instructions from the very start of the inspection from the corporate office were to be completely open and honest with FDA. She said that the hesitation in Mr. Kimbrell's response resulted from the stress under which they were operating. She said he was supposed to run all of the questions from

FDA through her before answering, so that was the reason she jumped in so quickly to clarify. She said she wanted us to know they intended to be completely open, and we told her we understood the stress everyone was under.

Investigator Douglas repeated to Ms. Horan his concern over the October 2004 incident. He told her he had attempted to follow-up an anonymous complaint regarding micro problems with Tom Gentle, the previous Plant Manager, and Mike Matis, the previous Quality Manager, during the inspection in February of 2005. (Refer to History section of this report for previous inspection summary.) Investigator Douglas said that they had checked with their corporate office and he was told only that the firm had placed some product on a micro hold and the product had been destroyed. He asked why they would not have reported the reason, and Ms. Horan said she couldn't answer that. He told her that considering what has since happened, he felt we had not choice but to review whatever information the firm had that would assure us the problem in October of 2004 had been contained. She said all she knew at the moment was that one of their experts took numerous swabs, but they never determined the source, and an extensive clean-up was performed. Ms. Horan reported that micro tests were run on finished product and environmental swabs, and that the *Salmonella* found was speciated in Omaha, but she did not recall it being *S. Tennessee*. Ms. Horan stated that she would ask the corporate office if and what information we could review concerning the 2004 occurrence. On 2/28/07, we received a summary of the October 2004 positive Salmonella test results from Mr. Don Jones, Sr. Director Enterprise Quality and Food Safety, EXHIBIT # 28 .

ADDITIONAL INFORMATION

On 2/26/07, we were notified by Ms. Chris Horan that they would be requiring a written request from the FDA before they could provide certain requested information. Ms. Horan indicated that the USDA normally provided such a request, and their legal department is requesting the same from us, so that this request would serve as a means of tracing the records provided to the FDA. This included information related to the findings of Salmonella during October of 2004 in finished product. Ms. Horan said that the firm usually requires such a written request, but they had been forgoing it up until now for expediency; however, some of the corporate people were not exactly sure what records we were asking for, and they needed a specific written request. She said that she thought the sticking point was the information concerning employee illnesses, and some of the corporate people were unfamiliar with some of the maintenance related issues, such as the cooling tower questions. We asked Ms. Horan who provided their legal counsel, and she reported that Mr. Tracy Beck in their corporate office was responsible for their legal department. We explained that we do not normally issue written requests and we would have to discuss this with our superiors in out district office before proceeding.

When we arrived at the firm on 2/28/07, Ms. Horan provided us with some of the records and information we had verbally requested earlier. The records were accompanied with a memo from Don Jones concerning these requests, EXHIBIT # 30.

On 2/26/07, Ms. Horan had discussed that they are trying to prepare the complete cleaning procedures for the plant. She said that they are planning on doing a complete HACCP concept cleaning, and they have started ordering supplies. Also, she said that the results from the environmental swabs and raw ingredient samples will impact the cleaning. Ms. Horan said that the HACCP plan will be re-assessed, and the firm's procedures will be reviewed and improvements made. She commented that their cleaning will be based on their test results as well as the FDA's. Ms. Horan stated that as soon as we are finished in the plant they will assemble their team and see where to start. During the down time at the plant, the employees have been receiving food sanitation training off-site. Management said that they are trying to raise awareness of all employees for food safety and food micro.

SAMPLES COLLECTED

On 2/15/07, we were joined by Chauncey A. Stephens and William (Bill) K. DuCloux, Microbiologists from the Southeast Regional Lab. The analysts collected environmental swab samples by aseptic technique on 2/15, 2/16, and 2/17. The analysts also assisted us with raw ingredient sampling and shipment of samples. Swab samples were collected with SpongeSicle 10ml Neutral Buffer, SSL-10NB produced by Biotrace International.

During the collection of environmental swabs throughout the plant, the firm was observed to collect their own samples, swabbing the exact area as the SRL analysts, and using the same subsample numbers. The location of each swab sample collected was recorded by the Investigators and also by the firm. On 2/17/07, the firm provided us with a description of each swab location collected. This list is attached to each collection report, included with this report, for the environmental swabs collected. The firm's swab samples were collected by Mr. Tuncan, and Mr. Kimbrell. The firm used BBL Culture Swab Collection and Transport System made by Copan for Becton, Dickinson and Company Sparks. It was noted that the firm was using swabs that had an expiration date of 2005/5, see EXHIBIT #29. Investigator Gray asked Mr. Tuncan if they were using the same set of swabs that they normally used to collect the monthly environmental swabs, and he said that he thought that it was the same swabs. When the expiration date of 2005 was pointed out, Mr. Tuncan stated that it didn't really matter. On 2/21/07, we noted that the firm had purchased several packs of spongesicle swabs, identical to the swabs used by the FDA analysts. The firm took photographs of each location, and noted the location of each swabbed area. During the collection of each finished product sample, the firm was observed to collect duplicate samples, selecting jars from the same case. The firm reportedly shipped their samples to ABC Laboratory in Gainesville, FL for Salmonella analysis. The sample results collected by the firm and analyzed by ABC Laboratory were not discussed with the Investigators during the inspection.

It should be noted that during the inspection, the firm did not dismantle any equipment that is not normally cleaned out of place in the wet wash room (i.e., votators, homogenizers). Mr. Gentle stated that they were waiting on our results to determine what and how deep to clean, therefore, if the results were negative, then they would not tear down anything out of the normal COP. We explained that we had planned on collecting environmental swabs in and around the equipment in the closed system, but if they were not already planning on tearing down this equipment, we would just collect

swabs of areas within reach. Mr. Gentle stated that some of the equipment tear down and replacement would take weeks to accomplish, so they preferred to wait for the lab results.

The following samples were collected during the inspection and transported to SRL for Salmonella analysis. A copy of the Collection Report for each sample is attached to this report.

Collected on 2/14/07:

Sample #366079 consisted of 15/18 oz. jars of Peter Pan Creamy Peanut Butter, lot code " PRD 11/09/06 EXP 11/09/08 ICOMTRADE" (this lot was manufactured for export);

Sample # 366080 consisted of 15/18 oz. jars of Great Value Crunchy Peanut Butter, lot code "2111634200 BEST BY 06 08 08";

Sample # 366076 consisted of 15/22 oz. jars of Peter Pan Crunchy Peanut Butter, lot code:2111632000 BEST BY MAY162008".

Collected on 2/15/07:

Sample #366077 consisted of 25 aseptically collected environmental swabs of various areas and equipment throughout the plant;

Sample # 366078 consisted of 25 aseptically collected environmental swabs of various areas and equipment throughout the plant;

Sample # 389113 consisted of 24 aseptically collected environmental swabs of various areas and equipment throughout the plant;

Sample # 389114 consisted of 25 aseptically collected environmental swabs of various areas and equipment throughout the plant.

Collected on 2/16/07:

Sample # 366081 consisted of 23 aseptically collected environmental swabs of various areas and equipment the plant;

Sample # 366082 consisted of 12/approximately 4 oz. subsamples of Peter Pan Vitamin Mineral Blend, lot 10701124;

Sample #366083 consisted of 6/approx. 4 oz subsamples of Soy Protein Concentrate, Lot No. 061206P;

Sample #366084 consisted of 10/approx. 4 oz. subsamples of Smart Choice Vitamin Mineral Blend, lot 10701123;

Sample #366085 consisted of 10/approx. 4 oz subsamples of Corn Syrup Solids, Lot No. KFRTS;

Sample #389115 consisted of approximately 12 ounces total of "Peter Pan" stabilizer collected in approximately equal portions from ports in powder room;

Sample #409450 consisted of approx. 4 ounces of "Smart Choice" stabilizer from port in powder room;

Sample #409451 consisted of approx. 8 ounces total of peanut oil collected in approx equal portions from ports on each bulk peanut oil tank;

Sample # 409452 consisted of 10 aseptically collected environmental swabs of empty jars taken at peanut bu

Sample # 409453 consisted of 10 aseptically collected environmental swabs of jar lids taken at peanut butter

Sample #409454 consisted of 7/approx. 4 oz. subsamples of corn starch, Lot # SG6K7052A.

Collected on 2/17/07:

Sample #409607 consisted of 10 aseptically collected environmental swabs of various areas and equipment throughout the plant;

Sample #409455 consisted of approx. 20 ounces total of U.S. Grade A Liquid Honey collected in approx. equal portions from 5 bulk totes, lot 0257D;

Sample #409456: consisted of approx 8 ounces total of Refiners Molasses collected from bulk tote bags, Lot S031H.

Sample #409457 consisted of 4/approx. 4 oz. subsamples of granulated sugar from bulk hopper to hammer mill;

Sample #409458 consisted of 3/approx. 4 oz. subsamples of Splenda Sucralose, Lot MM6M0356A0;

Sample #409459 consisted of 5/approx. 4 oz. subsamples of 6X Powdered Sugar, Lot W6191;

Sample # 409606 consisted of 8/approx. 4 ounce subsamples of salt from bulk tote bags; Lot B0367.

Collected on 2/21/07:

Sample #409786 consisted of 15/18 oz jars of Peter Pan Honey Roast Creamy Peanut Butter, coded "2111703700";

Sample #409787 consisted of 15/18 oz jars of Peter Pan No Sugar Added Creamy Peanut Butter Spread, coded "2111704400";

Sample #409788 consisted of 15/18 oz jars of Great Value Reduced Fat Peanut Butter Spread, coded "2111703000";

Sample #409789 consisted of 15/18 oz jars of Great Value Creamy Peanut Butter, coded "2111700600";

Sample #409790 consisted of 15/28 oz jars of Great Value Crunchy Peanut Butter, coded "2111700500";

Sample #409791 consisted of 15/28 oz jars of Great Value Creamy Peanut Butter, coded "2111702000";

Sample #409792 consisted of 15/18 oz jars of Great Value Reduced Fat Peanut Butter Spread, coded "2111702900";

Sample #409793 consisted of 15/28 oz jars of Peter Pan Honey Roast Creamy Peanut Butter, coded "2111703700";

Sample #409794 consisted of 15/17.6 oz jars of Peter Pan Plus Creamy Peanut Butter, coded "2111704500";

Sample #409795 consisted of 15/18 oz jars of Peter Pan Creamy Peanut Butter, coded "2111704400";

Sample #409796 consisted of 15/18 oz jars of Peter Pan Crunchy Peanut Butter, coded "2111703900";

Sample #409797 consisted of 15/18 oz jars of Peter Pan Honey Roast Crunchy Peanut Butter, coded "2111704500".

Collected on 2/26/07:

Sample #409798 consisted of 11/approximately 1 lb subsamples of raw, shelled peanuts collected from lots stored in raw storage bins numbered 1-2, 4 - 12. The subs collected were numbered according to the storage bin each sub was collected from.

Collected on 3/2/07:

Documentary Sample # 409799 documents the interstate commerce of 2800 cases of Peter Pan Products sh from ConAgra Grocery Products, Sylvester, GA to FTW Dry IMC, Fort Worth, TX on 2/14/07.

CLOSING DISCUSSION

Mr. Earl Ehret and Ms. Tabitha Giddens were the only members of management present during the closing discussion. The FDA-484 was issued to Mr. Ehret, and the FDA-463a was read and signed by Mr. Ehret. The Line Entry Permits from 7/31/06 to the present date and the listing of the manufacturer's and location of diaphragm valves in the plant were reviewed at this time. Mr. Ehret stated that they had started some surface cleaning, but the complete cleaning plan was still not finalized.

I told Mr. Ehret that a FDA-483, Inspectional Observations report, would not be issued at this time; however, the information gathered during the inspection would be documented in a report, which would be reviewed by the ATL-DO Compliance Branch, and FDA could pursue legal actions to achieve compliance. Mr. Ehret stated that he understood. I explained to management that the inspection was finished, and their cooperation throughout the inspection was appreciated.

EXHIBITS

EXHIBIT # 1: Organizational chart for ConAgra Foods; 1 page
EXHIBIT # 2: Distribution/inventory centers that receive finished product from the firm; 1 page
EXHIBIT # 3: Product inventory location as of 2/17/07 for products shipped from this plant; 14 pages
EXHIBIT # 4: Product codes or SKU numbers used by the firm to identify product

types and sizes; 3 pages
EXHIBIT # 5: Product labels; 19 pages
EXHIBIT # 6: Label for product packaged in 55 gallon drums; 1 page
EXHIBIT # 7: Letter of Inspection from the drum supplier; 1 page
EXHIBIT # 8: Labels of raw ingredients on hand at the plant during the inspection; 24 pages
EXHIBIT # 9: Certificate of Analysis (COA) for the sugar, soy protein concentrate and Splenda; 79 pages
EXHIBIT # 10: Supplier and list of raw ingredients/materials used in the firm's manufacturing operations; 3 pages
EXHIBIT # 11: Shipping Ticket and Hold notice for the shipment of 2 pallets of "wet" jars shipped to the firm on March of 2006; 2 pages
EXHIBIT # 12: List of the lubricants used in the plant; 2 pages
EXHIBIT # 13: Production code for suspect jars of peanut butter collected from consumer's involved in Salmonella outbreak; 1 page
EXHIBIT # 14: Finished Product Analysis results for suspect production codes; 10 pages
EXHIBIT # 15: Description and specifications for the cleaners and sanitizers used in the plant; 23 pages
EXHIBIT # 16: Partial package insert for the GeneQuence received on 2/16/07; 5 pages
EXHIBIT # 17: Complete package insert for GeneQuence received on 2/17/07; 10 pages
EXHIBIT # 18: Finished Product Analysis results for 2005; 255 pages
EXHIBIT # 18B: Finished Product Analysis results for 2005 (additional pages); 10 pages
EXHIBIT # 19: Finished Product Analysis results for 2006; 241 pages
EXHIBIT # 20: Environmental Swabs analysis results for 2005; 12 pages
EXHIBIT # 21: Environmental Swabs analysis results for 2006; 12 pages
EXHIBIT # 22: Plant diagrams of the firm; 3 pages
EXHIBIT # 23: Firm's HACCP plan for Peanut Butter products (Peter Pan and Great Value); 16 pages
EXHIBIT # 24: Firm's HACCP plan for Smart Choice and Reduced Fat Peanut Butter Spread (Creamy and Crunchy); 16 pages
EXHIBIT # 25: Product Reference Sheet for Exported Products; 5 pages
EXHIBIT # 26: Cooling Tower Service Reports; 5 pages
EXHIBIT # 27: Complaint Summary Report for Peanut Butter; 2 pages
EXHIBIT # 28: Salmonella Positive results summary for October 2004; 13 pages
EXHIBIT # 29: Culture Swab used by firm to collect environmental swabs; 1 page
EXHIBIT # 30: Memorandum from Don Jones, Sr. Director of Enterprise Food Safety and Quality,

dated 2/28/07, regarding requested documents; 1 page.

ATTACHMENTS
Attachment A: CDC memorandum's for Salmonella Tennessee Outbreak

FDA-482, Notice of Inspection; 2/14/07 and 2/15/07
FDA-484, Receipt for Samples; 2/14/07 and 3/2/07
Collection Reports for Samples collected during EI

Janet B Gray, Investigator

Jackie M. Douglas, Investigator

Peanut butter contamination pinned on moisture

By Josh Funk, AP business writer

OMAHA — Moisture from a leaky roof and faulty sprinkler helped salmonella bacteria grow and contaminate peanut butter at its Georgia plant last year, sickening more than 400 people nationwide, ConAgra Foods said Thursday.

The Omaha-based company conducted a nearly two-month investigation into the contamination and pledged to ensure that Peter Pan peanut butter is safe when it returns to stores in mid-July.

"Consumer safety and health is our top priority," ConAgra spokeswoman Stephanie Childs said. "We plan to do our best to regain consumer trust once Peter Pan returns to stores."

Childs said the company traced the salmonella outbreak to three problems at its Sylvester, Ga., plant last August.

The plant's roof leaked during a rainstorm, and the sprinkler system went off twice because of a faulty sprinkler, which was repaired.

The moisture from those three events mixed with dormant salmonella bacteria in the plant that Childs said likely came from raw peanuts and peanut dust.

The plant was cleaned thoroughly after the roof leak and sprinkler problem, but the salmonella remained and somehow came in contact with peanut butter before it was packaged, she said.

ConAgra recalled all its peanut butter in February after federal health officials linked it to cases of salmonella infection. At least 425 people in 44 states were sickened, and lawsuits have been filed against the company.

The recall covered all Peter Pan peanut butter and all Great Value peanut butter made at the Sylvester plant since October 2004. That plant is ConAgra's only peanut butter plant.

Peanuts grow underground and salmonella is present in the dirt, but generally any bacteria are killed when raw peanuts are roasted.

When making peanut butter, the nuts are again heated — above the salmonella-killing temperature of 165 degrees — as they are ground into a paste and mixed with other ingredients before being squirted into jars and quickly sealed.

Experts had speculated that salmonella would be most likely to contaminate peanut butter as it cooled and was placed in jars. At most plants, those steps take just minutes.

The company plans to redesign the plant to provide greater separation between raw peanuts and the finished product, Childs said. The plant will also get a new roof.

ConAgra plans to reopen the plant in early August.

Before this recall, none of ConAgra's recent routine testing had detected salmonella, so the company plans to develop a new procedure.

The Food and Drug Administration inspected the plant in February 2005 and found no problems, agency spokesman Michael Herndon has said. He did not immediately return calls Thursday.

ConAgra has hired an experienced microbiologist to oversee food safety, Childs said.

While renovations are being done, Peter Pan will be made at another company's plant, the company said. Childs declined to identify that manufacturing partner and said ConAgra had not decided whether that plant will continue making Peter Pan after its Sylvester factory reopens.

Since the recall shut down production, the Sylvester plant's roughly 100 workers have been paid to do maintenance work. Childs said it's not yet clear how the renovations will affect those employees.

Before the recall, ConAgra sold $150 million worth of peanut butter each year, Childs said.

In addition to peanut butter, the company's brand names include Healthy Choice, Chef Boyardee and Orville Redenbacher.

Salmonella sickens about 40,000 people a year in the U.S. and kills about 600. It can cause diarrhea, fever, dehydration, abdominal pain and vomiting.

But most cases of salmonella poisoning are caused by undercooked eggs and chicken. The only previously known salmonella outbreak in peanut butter — in Australia during the mid-1990s — was blamed on unsanitary plant conditions.

Find this article at:
http://www.usatoday.com/news/nation/2007-04-05-peanut-butter-contamination_N.htm

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Previous page : ConAgra to reopen renovated plant

ConAgra to reopen renovated plant

By George Reynolds

07/08/2007- **ConAgra is set to reopen this month the plant where jars of peanut butter were contaminated with salmonella, following the completion renovations costing $15m.**

Upgrade costs and the loss of production demonstrate the huge risks manufacturers are exposed to once the safety of their food is compromised.

The plant has been closed since February 14, after the US Centers for Disease Control and Prevention (CDC) linked about 600 cases of foodbourne illness across 47 states to consumption of Peter Pan and Great Value peanut butter products manufactured at the facility.

Works completed at the plant in Sylvester, Georgia, include roof repairs, new equipment installations and creating new processes to better separate raw materials and the finished product, according to reports in the *Associated Press*.

ConAgra said it had traced the contamination back to three incidents that took place in August 2006.

The contamination was most likely caused by moisture from a leaking roof and a faulty sprinkler system, which mixed with salmonella present in raw peanuts and dust at the plant.

The plant was cleaned thoroughly after the incidents, but the salmonella remained and came into peanut butter prior to packaging.

While the recall alone cost ConAgra a reported $66m, the company still faces lawsuits in several states.

Once production is underway, ConAgra Foods will begin shipping Peter Pan Peanut Butter to retailers this summer.

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Peter Pan Peanut Butter Salmonella Outbreak Marks Year Anniversary

Date Published: Friday, February 15th, 2008

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Yesterday marked the one year anniversary of the **Peter Pan and Great Value Peanut Butter recall**. The salmonella tainted peanut butters where recalled by ConAgra foods on February 14, 2007, after they were linked to an outbreak of salmonella poisoning across the country. Eventually, more than 600 cases of salmonella poisoning where blamed on Peter Pan and Great Value peanut butter manufactured at ConAgra's Sylvester, Georgia plant.

According to the **Centers for Disease Control** (CDC), the Peter Pan peanut butter salmonella outbreak extended to 47 states and two deaths were attributed to the salmonella tainted peanut butter. Though an unusually high incidence of salmonella poisoning was first noticed in Tennessee in November 2006, it is thought that the first illnesses attributable to the peanut butter may have occurred as early as March 2006. However, it wasn't until February 2007 that the CDC was able to trace the source of the illness to peanut butter produced by a ConAgra factory in Sylvester Georgia. ConAgra faulted a leaky roof and malfunctioning sprinkler system at its production facility for causing the Salmonella contamination. That same month, ConAgra finally issued a recall of its Peter Pan and Great Value brand peanut butter produced at that factory. The ConAgra plant in Georgia was closed for several months after the Peter Pan Peanut Butter salmonella outbreak.

Following the salmonella outbreak, the Food &Drug Administration FDA, as well ConAgra, came under fire for their slow response to the Peter Pan Peanut Butter problems. In April 2007, the Washington Post published documents proving that the FDA, as well as ConAgra, knew of contamination problems at the plant as far back as 2004. The agency took few corrective measures, assuming that ConAgra would address the situation itself. But ConAgra apparently did little to nothing to fix the problem.

The ConAgra plant that produced the salmonella peanut butter finally reopened last summer, with the company boasting that it had spent $15 million to repair problems that allowed the salmonella contamination to occur at the Georgia factory. Peter Pan Peanut Butter was also re-launched last August, amid a huge marketing blitz aimed at restoring customer faith in the product.

Unfortunately, the return of Peter Pan to stores did not end ConAgra's salmonella woes. In October 2007, the company's store brand and **Banquet Pot Pies** were tied to yet another salmonella outbreak. The CDC ultimately traced 272 cases of salmonella poisoning in 35 states to the tainted ConAgra pot pies. The US Department of Agriculture (USDA) investigation into the Banquet Pot Pie Salmonella outbreak found flaws with record keeping at the Missouri plant that produced the pot pies, as well as deficiencies with ConAgra's Hazard Analysis Critical Control plan that spells out what the company does to ensure product safety. The ConAgra Banquet Pot Pie Recall ended up costing ConAgra around $30 million.

This entry was posted on Friday, February 15th, 2008 at 1:43 pm and is filed under Legal News, Food Poisoning, Salmonella.

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News Releases

Missouri Firm Recalls Frozen Pot Pie Products For Possible *Salmonella* Contamination

Recall Release
FSIS-RC-044-2007

CLASS I RECALL
HEALTH RISK: HIGH

Congressional and Public Affairs
(202) 720-9113
Amanda Eamich

WASHINGTON, Oct. 11, 2007 - ConAgra Foods, a Marshall, Mo., firm, is voluntarily recalling an undetermined amount of all varieties of frozen pot pie products in commerce that may be linked to an outbreak of salmonellosis, the U.S. Department of Agriculture's Food Safety and Inspection Service announced today.

The following brands and all varieties, including chicken, turkey and beef, of frozen pot pie products are subject to this recall: [View Labels, PDF Only]

- Banquet
- Albertson's
- Food Lion
- Great Value
- Hill Country Fare
- Kirkwood
- Kroger
- Meijer
- Western Family

These frozen pot pies include all varieties in 7 oz. single serving packages bearing an establishment number "P-9" or "Est. 1059" printed on the side of the package.

These frozen pot pie products were distributed to retail establishments throughout the United States, Puerto Rico and the Caribbean islands. Based on product shelf life, these products could still be in consumers' freezers and it is important that consumers look for and return or discard and do not eat these products if they find them.

On October 9, FSIS issued a public health alert for these frozen pot pie products following an investigation by the Centers for Disease Control and Prevention (CDC) and State public health departments into a large cluster of illnesses caused by

Recommendations for Preventing Salmonellosis

Wash hands with warm, soapy water before and after handling raw meat and poultry. (Wash for at least 20 seconds). Also wash cutting boards, dishes and utensils with hot soapy water. Clean up spills right away.

Keep raw meat, fish and poultry away from other food that will not be cooked. Use separate cutting boards for raw meat, poultry and egg products and cooked foods.

Cook raw meat and poultry to safe internal temperatures before eating. The safe internal temperature for meat such as beef and pork is 160° F, and 165° F for poultry, as determined with a food thermometer.

Refrigerate raw meat and poultry within two hours after purchase or after one hour if temperatures exceed 90° F. Refrigerate cooked meat and poultry within two hours after cooking.

Salmonella that identified these products. The establishment voluntarily ceased operations on October 9; however FSIS continues its investigation to determine the source of contamination. The CDC, State public health departments and FSIS also continue investigation into the multi-state illness outbreak.

Consumers with questions about the recall may contact the Toll-Free Hotline at (866) 484-8671. Media with questions may contact company Director of Communications Stephanie Childs at (402) 595-6258. For more information consumers and media can also visit: www.conagrafoodscompany.com/corporate/index.jsp.

Consumption of food contaminated with *Salmonella* can cause salmonellosis, one of the most common bacterial foodborne illnesses. *Salmonella* infections can be life-threatening, especially to those with weak immune systems, such as infants, the elderly and persons with HIV infection or undergoing chemotherapy. The most common manifestations of salmonellosis are diarrhea, abdominal cramps, and fever within eight to 72 hours. Additional symptoms may be chills, headache, nausea and vomiting that can last up to seven days.

Consumers with food safety questions can "Ask Karen," the FSIS virtual representative available 24 hours a day at AskKaren.gov. The toll-free USDA Meat and Poultry Hotline 1-888-MPHotline (1-888-674-6854) is available in English and Spanish and can be reached from 10 a.m. to 4 p.m. (Eastern Time) Monday through Friday. Recorded food safety messages are available 24 hours a day.

#

www.fsis.usda.gov

Food Safety Questions? Ask Karen!
FSIS' automated response system can provide food safety information 24/7

Last Modified: October 11, 2007

USDA Recall Classifications	
Class I	This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.
Class II	This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.
Class III	This is a situation where the use of the product will not cause adverse health consequences.

washingtonpost.com

ConAgra Asks Stores to Quit Selling Pies

By JOSH FUNK
The Associated Press
Thursday, October 11, 2007; 10:44 AM

OMAHA, Neb. -- ConAgra Foods Inc. has asked stores to stop selling pot pies linked to a salmonella outbreak and is offering refunds for the turkey and chicken-filled meals.

The company and the U.S. Department of Agriculture on Wednesday defended their decision not to immediately recall the product.

ConAgra asked stores nationwide to pull the Banquet and generic brand chicken and turkey pot pies after two East Coast grocery chains made their own choice to remove the product from their shelves.

The pot pies made by ConAgra have been linked to at least 152 cases of salmonella in 31 states. The federal Centers for Disease Control and Prevention said at least 20 people have been hospitalized as part of the ongoing outbreak, but so far no deaths have been linked to the pot pies.

The company and federal officials warned customers not to eat the pot pies and to throw them away, and ConAgra is offering refunds.

ConAgra spokeswoman Stephanie Childs said the Omaha-based company decided with USDA officials that the consumer alert they issued Tuesday would be more appropriate than a recall.

"From the consumer perspective, there's not much difference," Childs said.

Even though the pot pies have not been recalled, Childs said ConAgra asked stores to pull all the pies with the identifying "P-9" code on them from store shelves and not sell them.

"We've taken this step knowing that we may need to take additional measures as we learn more from the ongoing investigation that is being led by the USDA," Childs said.

ConAgra officials have said they believe the pot pies are safe when they are thoroughly cooked according to the package directions. The company is revising the cooking directions on its pot pie packages to clarify how long the pies should be cooked in different microwaves.

The Giant Food and Stop & Shop supermarket chains said Wednesday that they were pulling the questionable pot pies from their stores' shelves as a precaution. Giant Food has 186 stores in Virginia, Maryland, Delaware and Washington, D.C., while Stop & Shop has 389 stores in seven northeastern states.

Amanda Eamich, a spokeswoman for the USDA's Food Safety and Inspection Service, said three investigators are at the ConAgra plant looking for problems with a specific product or production date, and without that connection, a recall wouldn't be ordered.

"As we continue our investigation, we felt it would be the best thing to do is get the word out," Eamich said.

ConAgra shut down the pot pie production line at its Marshall, Mo., plant, but the rest of the plant, which employs about 650 people, has continued operating, Childs said Wednesday. All of the pot pies made at the plant in question have "P-9" printed on the side of the box as part of a code above the use-by date.

The way the USDA has handled the pot pie concern highlights inconsistencies in the nation's food safety system.

Earlier this year, when the CDC linked ConAgra peanut butter to a salmonella outbreak that eventually sickened at least 625 people in 47 states, the company recalled all of its peanut butter. But peanut butter is regulated by the Food and Drug Administration, while pot pies are regulated by the USDA.

Salmonella sickens about 40,000 people a year in the U.S. and kills about 600. Most of the deaths are among people with weaker immune systems such as the elderly or very young.

Salmonella poisoning can cause diarrhea, fever, dehydration, abdominal pain and vomiting. Most cases are caused by undercooked eggs and chicken.

Consumers who want a refund for their pot pie should send the side panel of the package that contains the "P-9" location code to the following address: ConAgra Foods, Dept. BQPP, P.O. Box 3768, Omaha, NE 68103-0768. Consumers with questions can call the company toll free at 866-484-8671.

On the Net:

Centers for Disease Control Salmonella updates: http://www.cdc.gov/salmonella

ConAgra Foods Inc.: http://www.conagrafoods.com

United States Department of Agriculture
Food Safety and Inspection Service
Field Operations
Lawrence District Office
4920 Bob Billings Parkway
Lawrence, KS 66049-3855

October 23, 2007

Mr. David Ripley-Plant Manager
ConAgra Foods, Inc.
Est. 01059 M/00009 P
200 N. Banquet Drive
Marshall, MO 65340

NOTICE OF INTENDED ENFORCEMENT

Dear Mr. Ripley:

This serves as official notification by the Food Safety and Inspection Service (FSIS) of our intent to withhold the marks of inspection and suspend the assignment of inspection program personnel at ConAgra Foods, Inc., 200 N. Banquet Drive, Marshall, Missouri 65340 as per 9 CFR 500.4 (Rules of Practice).

Background/Authority

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) provides that it is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. These Acts give FSIS the authority, as designated by the Secretary of the Department of Agriculture, to prescribe rules and regulations describing sanitation requirements for inspected establishments. They also provide FSIS program personnel the authority to refuse to allow meat or meat food products, or poultry products, to be labeled, marked, stamped, or tagged as "inspected and passed" and to prevent the entry of products into commerce when the sanitary conditions of any such establishment are such that products are adulterated and provide definitions for the term "adulterated." Furthermore, the Act provides FSIS the authority to appoint inspectors from time to time to examine and inspect products, including the sanitary conditions of facilities. They also give FSIS program personnel the right to examine and inspect all carcasses and parts of carcasses that are further treated and prepared and the right to access and examine establishment records.

When the sanitary conditions of a facility are not properly maintained, FSIS can refuse to render inspection and indefinitely withdraw inspection from an establishment provided the establishment is afforded the right to an administrative hearing.

Under the authorities of the Acts, FSIS has prescribed rules and regulations required for establishments producing meat and poultry products, including the requirements pertaining to sanitation and Hazard Analysis and Critical Control Point (HACCP) (9 CFR Parts 416 and Parts 417) and other matters. FSIS has also developed Rules of Practice regarding enforcement (9 CFR Part 500). The Rules of Practice describe the types of enforcement action that FSIS may take and include procedures for taking a withholding action and or suspension, with or without prior notification, and for filing a complaint to withdraw a grant of federal inspection.

Findings/Basis for Action

The following information is provided to support this notification of intended enforcement for your facility:

FSIS Enforcement, Investigations, and Analysis Officers (EIAO) conducted a Food Safety Assessment (FSA), beginning on October 9, 2007, and ending on October 23, 2007, at your establishment. This FSA was initiated at the direction of the Lawrence District Office, to verify your establishment's compliance with 9 CFR 417 and 416.

This assessment revealed that your establishment failed to implement and maintain an adequate HACCP system, and Sanitation Standard Operating Procedures (SSOP's) to meet the requirements of 9 CFR 417 and 416 and to ensure food safety.

9 CFR 417 – HACCP

Hazard Analysis (9 CFR 417.2(a)(1) and 417.5(a)(1));

According to 9 CFR 417.2(a)(1) "Every *official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards."* In addition, 9 CFR 417.5(a)(1) requires that *"The establishment shall maintain the following records documenting the establishment's HACCP plan: The written hazard analysis prescribed in 417.2(a) of this part, including all supporting documentation."*.

1. In your hazard analysis, you have acknowledged that vegetative pathogens are a potential biological hazard in the ingredients that you receive and have defined that this includes *Listeria monocytogenes, Salmonella,* and *E. coli* O157:H7. You have determined that a potential biological hazard (vegetative and spore forming pathogens, rodents, insects) is not reasonably likely to occur at steps for receiving ingredients in your hazard analyses for your pot pie line, dinner lines, Dake line and skillet line. This includes but is not limited to when receiving ingredients for slicing/chipping/dicing (meat/poultry), batching and blending, and dough mixing for your pot pies. Your basis for this decision states that "Raw materials received are evaluated for adulteration, contamination and temperature (if applicable) at receipt. Unacceptable conditions (trailer, container, or product) are cause for rejection. Suppliers are required to have a Supplier Letter of Guarantee on file with ConAgra Corporate Purchasing group."

   Your establishment provided documents describing the specifications for vegetables (potatoes, peas, carrots) that you use in your pot pies. These documents include microbiological requirements for *E. coli, Salmonella and Listeria.* Your establishment said that they do not request documentation from your suppliers on whether the products that you receive have been tested to determine if they are meeting your requirements. Your microbiology sampling (PP-13) for ingredients includes sampling incoming ingredients for TPC, Coliform, yeast and mold, but does not include sampling for pathogens. You did not provide supporting documentation to demonstrate a correlation between TPC, Coliform, yeast and mold counts to the probability of these ingredients being contaminated with *Salmonella.* The documentation that you have provided does not support your decision that vegetative pathogens including *salmonella* are not reasonably likely to occur when receiving ingredients in each of your processes. Therefore, you have failed to meet the requirements of 9 CFR 417.5(a)(1).

   In addition, you included a document titled "Scientific Bases and Justifications associated with CCP's" in the HACCP plan for your pot pie line which states that "The pot pie contains components other than the fully cooked meat and gravy portions that may present a biological hazard" and "There is no processing cooking step to eliminate vegetative pathogens that may then be line blended with the fully cooked meat and gravy. Lethality is addressed through the handling and cooking instructions on the finished product

package". Your documentation for the Dake line, dinner line and skillet/crock pot line included similar statements indicating that lethality is addressed through the handling and cooking instructions on the finished product package.

The labels on your Banquet pot pies clearly state on the front panel "READY IN 4 minutes MICROWAVABLE", even though the cooking directions on the back of the label requires more time in a low wattage microwave with a three minute stand time. In addition, the documentation that you provided states that "Standing time is an important component of achieving the target temperature of ≥160° F." The labels on other store brands also indicate that they are ready in four minutes. The labels on your Great Value pot pie include similar cooking instructions on the back panel, but states "Microwave 6 minutes" on the front. Your validation records did not explain why the labels would indicate four minutes on the front of some brands of product and six minutes on the front of the Great Value brand. Your validation documentation did not indicate if you had taken into consideration how the consumer is likely to interpret the cooking instructions or if the consumer will actually prepare the product according to the instructions under normal conditions of use, especially with the statements on the front of the packages which do not reflect the need to let the products stand after heating.

The cooking directions on the pot pie labels include four minutes in a "Medium OR High Wattage Microwave" and six minutes in a "Low Wattage Microwave". However, your directions do not indicate what is considered to be a high, medium or low watt microwave. Again, your validation documentation did not indicate if you had considered how the consumer may interpret the cooking directions or if the consumer will actually prepare the product according to the directions under normal conditions of use, especially if they did not know whether they were using a high, medium or low wattage microwave.

Your establishment has not provided documentation to support that some of the temperatures reported in your cooking instruction validation documentation for frozen dinners will provide an adequate lethality.

For example, in some of your Banquet meals the chicken fingers only reached a temperature of ≥127° F, the BBQ chicken reached a temperature of ≥141° F and the pork only reached a temperature of ≥142° F. You indicated that these meat/poultry are fully cooked components. However, they are packaged with other ingredients that are not fully cooked and your documentation did not address cross contamination between these ingredients and whether these temperatures will provide an adequate lethality if cross contamination occurs.

In addition, you validation documentation indicates that the corn in your Banquet Chicken Fried Beef Steak dinner only reached ≥139° F. Your establishment has not provided documentation to support whether this temperature will provide an adequate lethality.

As another example, your validation documentation indicates that in the GE large electric conventional oven the pudding in your Kid Cuisine Chicken Breast Nugget meal only reached 142° F with a heating time of 18 minutes. Your establishment has not provided documentation to support whether this temperature will provide an adequate lethality.

The documentation provided by the establishment does not support that lethality is addressed through the handling and cooking instructions on the finished product package as stated in your HACCP records titled "Scientific Bases and Justifications associated with CCP's". Therefore, you have failed to meet the requirements of 9 CFR 417.5(a)(1).

By failing to provide documentation to support the decision that a biological hazard including *Salmonella* is not reasonably likely to occur when receiving ingredients for your pot pies and that lethality is addressed through the handling and cooking instructions on the finished product package. Your establishment has failed to demonstrate

that the biological hazard of vegetative pathogens including *Salmonella* are not reasonably likely to occur and will not affect the safety of the products for human consumption. This precludes FSIS from determining that the food safety hazards are being controlled and that the products are not adulterated.

Salmonella can cause salmonellosis, one of the most common bacterial foodborne illnesses. *Salmonella* infections can be life threatening, especially to those with weak immune systems, such as infants, the elderly and persons with HIV infection or undergoing chemotherapy. The most common manifestations of salmonellosis are diarrhea, abdominal cramps, and fever within eight to 72 hours. Additional symptoms may be chills, headache, nausea and vomiting that can last up to seven days.

Corrective Actions 9 CFR 417.2(c)(5) and 417.3:

According to 9 CFR 417.3, *"The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective actions, to ensure: 1. The cause of the deviation is identified and eliminated; 2. The CCP will be under control after the corrective action is taken;3. Measures to prevent a recurrence are established; and 4. No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce."*

2. Your monitoring records dated 7/20/07 for CCP-2 on their fryer line indicates that the product temperature was 73° at 10:40 and again at 10:50. The record for the 10:40 check indicates that the product was taken to the freezer. The record for the 10:50 check indicates that the product was taken to the production line. However, your records do not indicate that you continued to monitor these products to determine if your critical limit in your HACCP plan was met for this CCP, which requires that the product be cooled from 130° F to 80° F within 1.5 hours and 80° F to 40° F within 5 hours. Your record review documentation for this CCP was signed indicating that establishment personnel had reviewed the records and that product for the period from 10:30-12:30 had met requirements. Your records did not include documentation that you had taken corrective actions as specified in your HACCP plan to meet the requirements of 9 CFR 417.3(a), even though your records do not indicate that the product had met the critical limit.

Not meeting a critical limit indicates that the CCP is out of control, and therefore a potential for the development of a health hazard exists.

Verification 9 CFR 417.2(c)(7) and 417.4(a)(2):

9 CFR 417.2(c)(7) states that *"The HACCP plan shall at a minimum: List the verification procedures and the frequency with which those procedures will be performed, that the establishment will use in accordance with 417.4 of this part."* According to 9 CFR 417.4(a)(2), *"Ongoing verification activities include, but are not limited to: (i) The calibration of process-monitoring instruments; (ii) Direct observation of monitoring activities and corrective actions; and (iii) The review of records generated and maintained in accordance with 417.5(a)(3) of this part."*

3. Your HACCP plans for the pot pie line, dinner lines, and Dake line do not list record review at a specific frequency as an on-going verification procedure, as required by 9 CFR 417.4(a)(2)(iii).

4. Your HACCP plans for the fryer line and skillet meal/crock pot line includes a verification procedure for reviewing the calibration records at least once per week and you do have a pre-requisite program for calibrating your thermometers. However, this is not referenced in your HACCP plans for the fryer line or skillet meal/crock pot line and the HACCP plans do not include a procedures for calibrating your thermometers at a specific frequency as required by 9 CFR 417.4(a)(2)(i).

5. Your daily gravy system thermometer verification records indicate that on numerous dates, including 7/31/2007, 8/2/2007, 8/3/2007, 9/17/2007 and 9/20/2007, the difference between the verifying thermometer and the panel view temperature was greater than the five degrees specified in the procedures in your HACCP plan. However, your records do not indicate that these instruments were recalibrated to ensure their accuracy. Your establishment has not properly performed the procedures in your HACCP plan for the calibration of process monitoring instruments as required by 9 CFR 417.2(c)(7) in accordance with 9 CFR 417.4(a)(2)(i).

Since HACCP plans rely on accurate measurements when monitoring critical control points to ensure that critical limits are met, it is important to use properly calibrated process monitoring instruments. The goal of the calibration procedures is to ensure that all measurements are accurate. If the measurement of a particular parameter is not accurate, then the critical limit may not have been met. Not meeting a critical limit indicates that the CCP is out of control, and therefore a potential for the development of a health hazard exists.

On-going verification activities are key functions in the implementation of a HACCP plan to evaluate the day to day activities at a CCP to determine compliance with the specifics of the HACCP plan. Without adequate verification, FSIS cannot be sure that the food safety hazards are being controlled and safe products are being produced.

HACCP Records (9 CFR 417.5):

9 CFR 417.5(a)(2) states "*The establishment shall maintain the following records documenting the establishment's HACCP plan: (1) The written hazard analysis prescribed in 417.2 of this part, including all supporting documentation; (2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.*"

6. You did not provide documents supporting the selection of your frequencies for the verification procedures in your HACCP plans as required by 9 CFR 417.5(a)(2).

According to 9 CFR 417.5(a)(3) "*The establishment shall maintain the following records documenting the establishment's HACCP plan: Records documenting the monitoring of CCP's and critical limits , including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot.*" In addition, 9 CFR 417.5(b) which states that "*Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.*"

7. Your monitoring records include a space at the bottom of the form identified as "direct observation & verification". Establishment management explained that these are used to document your direct observation verification and the verification temperatures that are to be taken at the same time as specified in your HACCP plans for the pot pie line, dinner lines and Dake line. These records utilize the same date as the monitoring record and include the time, signature or initials and the verification temperature. However, these records do not include the results of the direct observation verification as required by 9 CFR 417.5(a)(3). These records also do not include the time recorded as required by 9 CFR 417.5(b).

8. Your record review verifications for CCP-1 for the pot pie line, dinner lines, Dake line and fryer line are recorded on a record review form that states that they have reviewed the records indicate that products for a specific time period have met requirements. These records also include the date and is signed or

initialed by the person making the entry. However, these records do not include the time recorded as required by 9 CFR 417.5(b).

9. Your record review verifications for CCP-2 for the pie line include a hand written entry in the upper margin of your monitoring records indicating that the record was "reviewed" and includes the date and is signed or initialed by the person making the entry. However, these records do not include the results of these record reviews as required by 9 CFR 417.5(a)(3).

10. Your thermometer verification records do not include the time recorded as required by 9 CFR 417.5(b).

Sanitation 9 CFR 416:

The Poultry Products Inspection Act, 21 U.S.C. § 456 and the Federal Meat Inspection Act, 21 U.S.C. § 608, gives the Secretary of Agriculture the authority to prescribe regulations (9 CFR 416) regarding sanitation in official establishments. 9 CFR 416.12 requires establishments to have written SSOP's that describe all the procedures they will conduct to prevent contamination of product. 9 CFR 416.13 requires them to perform all of these procedures as prescribed in the SSOP's. 9 CFR 416.14 requires an establishment to routinely evaluate their SSOP's and to revise them as necessary to keep them effective and current. 9 CFR 416.15 outlines the necessary corrective actions the establishment must take to ensure that sanitary conditions of product and product contact surfaces are adequately restored when a noncompliance is detected by either FSIS or establishment involving product or product contact surfaces. 9 CFR 416.16 outlines the record keeping requirements for both monitoring and implementation of corrective actions.

Sanitation Standard Operating Procedures (SSOP's):

According to 9 CFR 416.13(c), *"Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's. and 9 CFR 416.14 "Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operation, or personnel.*

1. The observations conducted by FSIS during the pre-operational plant inspections, and in correlating your program, which indicate that equipment will be disassembled and inspected. Therefore, in not breaking down these pipes other than at the connection sites for the pumps and holding tanks to perform an organoleptic technique of inspection, you have failed to demonstrate that effective evaluation of that cleaning procedure has been accomplished for these pipes used for edible product. This does not meet the requirements of their SSOP's according to 9 CFR 416.13(c). In addition, your environmental swabbing program that is used before and during operations to detect coliform and aerobic plate counts of the equipment is utilized to evaluate the effectiveness of your sanitation. You provided results as an example pertaining to the pie line for one day 5/02/2007 and a graph chart that reflects a period during 8/07/2006 to 9/27/2007 of the swabs collected. When questioning about what actions are taken when there is a spike in the graph, you indicated that if trends are evident then an evaluation of the area and/or corrective actions may be taken but no documentation of actions are recorded and that no base line or action limit is used. Therefore, by not effectively utilizing the results recorded or effectively monitoring procedures. You failed to demonstrate effective evaluation of their SSOP's according to 9 CFR 416.14.

Conclusion:

Meat and Poultry products are an important part of the nation's supply of food. They are consumed throughout the nation and the major portion thereof moves in interstate or foreign commerce. The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) provides

that it is essential in the public interest that the health and welfare of consumers be protected by assuring that meat products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. The Act gives FSIS the authority, as designated by the Secretary of the Department of Agriculture, to prescribe rules and regulations describing sanitation requirements for inspected establishments. They also provide FSIS program personnel the authority to refuse to allow meat or meat food products, or poultry products, to be labeled, marked, stamped, or tagged as "inspected and passed" and to prevent the entry of products into commerce when the sanitary conditions of any such establishment are such that products are adulterated and provide definitions for the term "adulterated."

Title 21 U.S.C. 601(m)(4) of the FMIA states "The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances; (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health" and 21 U.S.C. 453(g)(4) of the PPIA states "The term "adulterated" shall apply to any poultry product under one or more of the following circumstances; (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health"

Under the authorities of the Acts, FSIS has prescribed rules and regulations required for establishments producing meat and poultry products, including the requirements pertaining to sanitation and Hazard Analysis and Critical Control Point (HACCP) (9 CFR 416 and 417) and other matters. FSIS has also developed Rules of Practice regarding enforcement (9 CFR 500). The Rules of Practice describe the types of enforcement action that FSIS may take and include procedures for taking a withholding action and or suspension, with or without prior notification, and for filing a complaint to withdraw a grant of Federal inspection.

The assessment conducted at your establishment revealed that your establishment was not in compliance with the regulatory requirements for Sanitation Standard Operating Procedures (SSOPs) 9 CFR 416.13 and 416.14; and Hazard Analysis and Critical Control Points (HACCP) 9 CFR 417.2 and 417.5.

These findings demonstrate that your HACCP system is inadequate as prescribed in 9 CFR Part 417.6, which states that *"A HACCP system may be found to be inadequate if:*
(a) The HACCP plan in operation does not meet the requirements set forth in this part;
(b) Establishment personnel are not performing tasks specified in the HACCP plan;
(c) The establishment fails to take corrective actions, as required by 417.3 of this part;
(d) HACCP records are not being maintained as required in 417.5 of this part"

These findings also demonstrate that your establishment's Sanitation Standard Operating Procedures have not been properly implemented or maintained.

FSIS has specified, through regulations 9 CFR 416 and 417, the conditions under which meat and poultry products must be produced. These regulations are essential, integral components of the regulatory system, and the failure, inability or unwillingness of an establishment to comply with these food safety regulations effectively precludes FSIS from making the determination that meat and poultry products are wholesome, not adulterated, and entitled to bear the marks of inspection.

Therefore, in accordance with FSIS Rules of Practice, 9 CFR 500.4(a) and (b) we are notifying you of our intent to withhold the marks of inspection and suspend the assignment of inspectors at your facility.

Please be advised that, as a federally inspected establishment, you are expected to comply with the Federal Meat Inspection Act (FMIA) and all appropriate FSIS regulations. The regulations require establishments to take appropriate action when either establishment management or FSIS determines that the establishment's HACCP and/or SSOP system is inadequate. We are giving you the opportunity at this time to demonstrate: (a) why a

decision that your SSOP/HACCP systems are inadequate should not be made and (b) that you have achieved regulatory compliance.

Please provide this office a written response addressing each of those issues identified in the preceding pages within three (3) business days of the receipt of this letter. We will determine further actions, if any, based on your response.

Your response addressing the numbered issues above is expected to include the following three [3] things:

A.) A description of your findings concerning your HACCP system and SSOP's; a description of any planned or completed revisions made to your HACCP system and/or SSOPs, and improvements in the implementation of these programs. Your description is expected to include documentation of any new information and any changes already made, i.e., copies of new supporting documents and copies of any revised procedures.

B.) Details of your action plan, which must include all corrective/preventative measures you are taking or have taken. Again, if your action plan includes revisions to your HACCP procedures and/or SSOP's, please include documentation to demonstrate that those changes are being executed, i.e. HACCP, SSOP, or other applicable records, sufficient to demonstrate the proper execution of the new procedures.

C.) Please include a description of any other actions taken or to be taken, such as changes to the labeling of your product. For any action plan revisions or measures not yet completed, include the anticipated dates of completion and implementation.

If you have any questions regarding this matter, please contact me at the Lawrence District Office, 4920 Bob Billings Parkway, Lawrence Kansas 66049. The phone number at this office is 785-841-5600 and the fax number is 785-841-5623.

Sincerely,

Wm. M. Walker
District Manager

cc: A. Tawadrous, EARO
FO/QER
K. Goin, RM
R. Kelly, DDM
L. Johnson, DDM
D. Wingert, DA
J. Barham, CS
L. Darr, FLS
J. Walters, CSI/IIC

Investigation of Outbreak of Human Infections Caused by *Salmonella* I 4,[5],12:i:-

Cases of *Salmonella* I 4,[5],12:i:- infection with the outbreak strain, by state, January 1 to October 29, 2007

Click map to view a larger image.

Questions and Answers Related to the Outbreak of *Salmonella* infections from Pot Pies

Information updated as of October 29, 2007

Click Here for Advice to Consumers

***NOTE:** This is the last planned web update on this outbreak.*

CDC is collaborating with public health officials in multiple states across the United States and with the U.S. Department of Agriculture□s Food Safety and Inspection Service to investigate an ongoing multi-state outbreak of *Salmonella* I 4,[5],12:i:- (pronounced □four five twelve eye minus□) infections in humans. An investigation that used interviews comparing foods eaten by ill and well persons is showing that eating Banquet brand pot pies produced by the ConAgra Foods company is the likely source of the illness.

Between January 1, 2007 and October 29, 2007, at least 272 isolates of *Salmonella* I 4,[5],12:i:- with an indistinguishable genetic fingerprint have been collected from ill persons in 35 states. Ill persons whose *Salmonella* strain has this genetic fingerprint have been reported from Arizona (1 person), Arkansas (4), California (18), Colorado (9), Connecticut (7), Delaware (5), Florida (2), Georgia (2), Idaho (11), Illinois (7), Indiana (3), Iowa (1), Kansas (4), Kentucky (9), Massachusetts (7), Maryland (7), Maine (2), Michigan (3), Minnesota (7), Missouri (18), Montana (6), Nevada (6), New York (10), North Carolina (2), Ohio (11), Oklahoma (1), Oregon (4), Pennsylvania (18), Tennessee (6), Texas (4), Utah (12), Virginia (9), Vermont (2), Washington (27), Wisconsin (24), Wyoming (3). Their ages range from <1 to 89 years with a median age of 18 years; 51% of ill persons are female. At least 65 people have been hospitalized. No deaths have been reported.

Investigation of the Outbreak

CDC coordinated a case-control study designed to identify the source of these infections. For this study, a case was defined as *Salmonella* infection on or after August 1, 2007, with a strain that had the outbreak genetic fingerprint. Eating a Banquet brand pot pie was significantly associated with illness. State health departments are collecting and testing pot pie products recovered from patients□ homes. To date, three patients□ pot pies have yielded *Salmonella* I4,[5],12:i:- isolates with a genetic fingerprint indistinguishable from the outbreak pattern.

Clinical features

Most people infected with *Salmonella* develop diarrhea, fever, and abdominal cramps 12□72 hours after infection. Infection is usually diagnosed by culture of a stool sample. The illness usually lasts 4 □ 7 days. Although most people recover without treatment, severe infections may occur. Infants, elderly persons, and people with impaired immune systems are more likely than others to develop severe illness. In severe infection, *Salmonella* spreads from the intestines to the bloodstream and then to other body sites, and death can occur if the person is not treated promptly with antibiotics.

Advice to consumers

On October 11, 2007, ConAgra Foods issued a voluntary recall of frozen pot pies that may be linked to this outbreak. The following brands of frozen pot pie products are subject to this recall:

- Banquet
- Albertson□s (sold at Albertson□s)
- Food Lion (sold at Food Lion)
- Great Value (sold at Wal-Mart)
- Hill Country Fare (sold at HEB)
- Kirkwood (sold at Aldi)
- Kroger (sold at Kroger)
- Meijer (sold at Meijer)
- Western Family (now discontinued; previously sold at a variety of small retailers)

These frozen pot pies include all varieties in 7 oz. single serving packages bearing an establishment number □P-9□ or □Est. 1059□ printed on the side of the package. These frozen pot pie products were distributed to retail establishments throughout the United States, Puerto Rico, and the Caribbean islands. These products could still be in consumers□ freezers, so it is important that consumers look for and return or discard these products.

Consumers should not eat these products.

U.S. Department of Agriculture Food Safety and Inspection Service recall notice:

www.fsis.usda.gov/News_&_Events/Recall_044_2007_Release/index.asp

Page last modified: October 29, 2007
Content Source: **National Center for Zoonotic, Vector-Borne, and Enteric Diseases (ZVED)**

ConAgra Banquet Pot Pie Salmonella Victims Now Number 272, CDC Says

Date Published: Wednesday, October 31st, 2007

The ConAgra **Banquet Pot Pie Salmonella** outbreak has extended to 35 states, where the tainted pot pies have sickened 272 people. According to the Centers for Disease Control (CDC), at least 65 victims have been hospitalized, but there have been no deaths connected to the ConAgra pot pie recall.

The number of **Salmonella** victims has more than doubled since ConAgra's Banquet and store brand pot pies were first linked to 139 cases of Salmonella poisoning throughout the country on October 9. That day, ConAgra issued a health alert about the Salmonella pot pie outbreak, warning consumers not to eat any of its 7-ounce store brand or Banquet Pot Pies with the codes "P-9" or "Est 1059" on the package. Despite the health alert, ConAgra did not recall the tainted Banquet pot pies. Instead, ConAgra tried to deflect blame for the Salmonella pot pies by claiming that consumers caused the outbreak by failing to cook the pies properly.

On October 11, ConAgra finally did issue a pot pie recall. The day prior to the recall announcement, media outlets reported that two state health officials from Minnesota and Oregon had formally requested that ConAgra officially recall the pies, but were rebuffed. Shortly after those reports circulated, ConAgra announced the pot pie recall. Included in the pot pie recall notice were all varieties of Banquet Pot Pies, as well as ConAgra-produced generic brand pot pies under the following labels: Albertson's, Food Lion, Great Value, Hill Country Fare, Kirkwood, Kroger, Meijer and Western Family. The Salmonella contaminated pot pies were sold in all fifty states, as well as in Puerto Rico and the Caribbean Islands.

According to the latest CDC report on the ConAgra pot pie Salmonella outbreak, all 272 victims tested positive for the same strain of the bacteria. The CDC has linked those cases to the consumption of Banquet Pot Pies, and the same Salmonella strain was also found in three ConAgra pot pies purchased by victims. Washington state has been struck with the highest number of Salmonella cases, with 27. Wisconsin has had 24, while California, Missouri and Pennsylvania each had 18. The CDC says that the Salmonella outbreak is still ongoing, so consumers are urged to check their freezers for any Banquet or store brand pot pies covered by the recall.

This is the second time this year that ConAgra has had to issue a large-scale product recall because of Salmonella dangers. In February, the company recalled its Peter Pan and Great Value Peanut Butter after it was blamed for a Salmonella outbreak that sickened more than 600 people in 47 states. Considering how long ConAgra allowed its Salmonella tainted pot pies to stay in circulation, it would not be surprising if this latest outbreak became just as extensive.

This entry was posted on Wednesday, October 31st, 2007 at 10:40 am and is filed under Legal News, Defective Products, Health Concerns, Product Recalls.

You can leave a response, or trackback from your own site.

« Topps Ground Beef Recall, E. Coli Outbreak Started with Canadian Beef

CPSC Head Says She Won't Step Aside, Despite Criticism Over Toy Recalls »

Leave a Reply

Name

Mail (will not be published)

Website

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Castleberry's Announces Voluntary Recall of Chili Products

Contact:
Castleberry's Consumer Hotline
1-888-203-8446

FOR IMMEDIATE RELEASE -- Augusta, Georgia -- July 18, 2007 -- Castleberry's Food Company today announced that it is voluntarily recalling the following products: Castleberry's Hot Dog Chili Sauce, 10 oz can (UPC 3030000101), Austex Hot Dog Chili Sauce, 10 oz can (UPC 3030099533), Kroger Hot Dog Chili Sauce, 10 oz can (UPC 1111083942), Morton House Corned Beef Hash, 15 oz can (UPC 7526665830), Cattle Drive Chili with Beans, 15 oz can (UPC 3030001515), Southern Home Corned Beef Hash, 15 oz can (UPC 0788015360), Meijer Corned Beef Hash, 15 oz can (UPC 4125095229), Castleberry's Chili with Beans, 15 oz can (UPC 3030001015), Castleberry's Barbecue Pork, 10 oz can (UPC 3030000402) and Bunker Hill Chili No Beans, 10 oz can (UPC 7526604112).

Castleberry's is working with the U.S. Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Centers for Disease Control and Prevention (CDC) to investigate possible contamination of these products with *Clostridium botulinum*, a bacterium which can cause botulism, a life-threatening illness. Botulism can cause the following symptoms: general weakness, dizziness, double-vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these problems should seek immediate medical attention.

This recall only affects the products listed above with a "best by" date of APR30 2009 through MAY22 2009. The "best by" date can be found either on the top or bottom of the can. Consumers who have any of these products should discard them. Consumers should not use these products even if they do not look or smell spoiled. Consumers may return the label to the location where the product was purchased for a full refund.

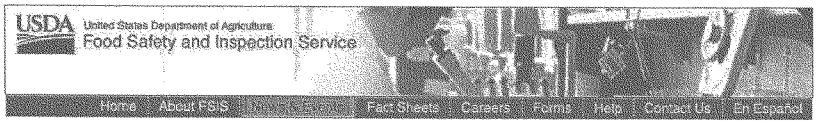
Castleberry's was notified by the FDA of four potential cases of botulism involving individuals who ate these products. "We are taking this precautionary measure to ensure the safety of our consumers," said Steve Mavity, SVP Technical Services/Quality Assurance for Castleberry's. "We will continue to work closely with the FDA, USDA, and CDC."

Consumers with any questions or concerns about this recall should go to Castleberry's website (http://www.castleberrys.com) or call Castleberry's consumer hotline at 1-888-203-8446.

####

FDA Press Release (July 18, 2007)

RSS Feed for FDA Recalls Information [what's this?]



News Releases

Georgia Firm Recalls Canned Meat Products That May Contain *Clostridium botulinum*

Recall Release
FSIS-RC-033-2007

CLASS I RECALL
HEALTH RISK: HIGH

Congressional and Public Affairs
(202) 720-9113
Amanda Eamich

WASHINGTON, July 19, 2007 - Castleberry's Food Company, an Augusta, Ga., establishment owned by Bumble Bee Foods, LLC, is voluntarily recalling approximately 721,389 pounds of canned meat products that may contain *Clostridium botulinum* as a result of an equipment malfunction, the U.S. Department of Agriculture's Food Safety and Inspection Service announced today.

The following products are subject to recall: [View Labels | PDF Document, 1.2MB]

- 10-ounce cans of "*Castleberry's* BUNKER HILL, ORIGINAL Chili NO BEANS." Each label bears the establishment number "EST. 195" inside the USDA seal of inspection. The bottom of each can is stamped with a "best by" date of "5/22/2009."
- 15-ounce cans of "*Castleberry's* CHILI WITH BEANS." Each label bears the establishment number "EST. 195" inside the USDA seal of inspection. The bottom of each can is stamped with a "best by" date of "5/17/2009."
- 10-ounce cans of "*Castleberry's* HICKORY SMOKED, OVEN ROASTED, WITH SKINS, BARBECUE PORK IN BARBECUE SAUCE." Each label bears the establishment number "EST. 195" inside the USDA seal of inspection. The bottom of each can is stamped with a "best by" date of "5/17/2009."
- 15-ounce cans of "Cattle Drive CHILI WITH BEANS." Each label bears the establishment number "EST. 195" inside the USDA seal of inspection. The bottom of each can is stamped with a "best by" date of "4/30/2009," "5/10/2009" or "5/21/2009."
- 15-ounce cans of "Meijer CORNED BEEF HASH." Each label bears the establishment number "EST. 195" inside the USDA seal of inspection. The bottom of each can is stamped a "best by" date of "5/3/2009."
- 15-ounce cans of "MORTON HOUSE *Corned Beef Hash*." Each label bears the establishment number "EST. 195" inside the USDA seal of inspection. The bottom of each can is stamped with a "best by" date of "5/3/2009."
- 15-ounce cans of "SOUTHERN HOME CORNED BEEF HASH." Each label bears the establishment number "EST. 195" inside the USDA seal of inspection. The bottom of each can is stamped with a "best by" date of "5/3/2009."

The canned meat products were produced between April 30 and May 22, 2007 and were distributed to retail establishments in

Alabama, Arkansas, California, Connecticut, Delaware, Florida, Georgia, Indiana, Louisiana, Michigan, Mississippi, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, West Virginia and Wisconsin.

The problem regarding the equipment malfunction was discovered during an investigation into illnesses in Indiana and Texas. The investigation led to a recall by the Food and Drug Administration of three types of meatless hotdog chili sauce. There have been no reports of illness from consumption of the products listed in this news release.

Botulism is a rare but serious paralytic illness caused by a nerve toxin. Symptoms of botulism include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness. The illness can cause paralysis, respiratory failure and death. Symptoms usually occur from 18 to 36 hours after eating contaminated food. Anyone concerned about an illness should contact a physician.

Consumers with questions about the recall should contact company Consumer Hotline at (888) 203-8446. Media with questions about the recall should contact the company public affairs representative Della Sweetman at (619) 200-0436 or Doug McGraw at (212) 453-2202.

Consumers with food safety questions can "Ask Karen," the FSIS virtual representative available 24 hours a day at AskKaren.gov. The toll-free USDA Meat and Poultry Hotline 1-888-MPHotline (1-888-674-6854) is available in English and Spanish and can be reached from 10 a.m. to 4 p.m. (Eastern Time) Monday through Friday. Recorded food safety messages are available 24 hours a day.

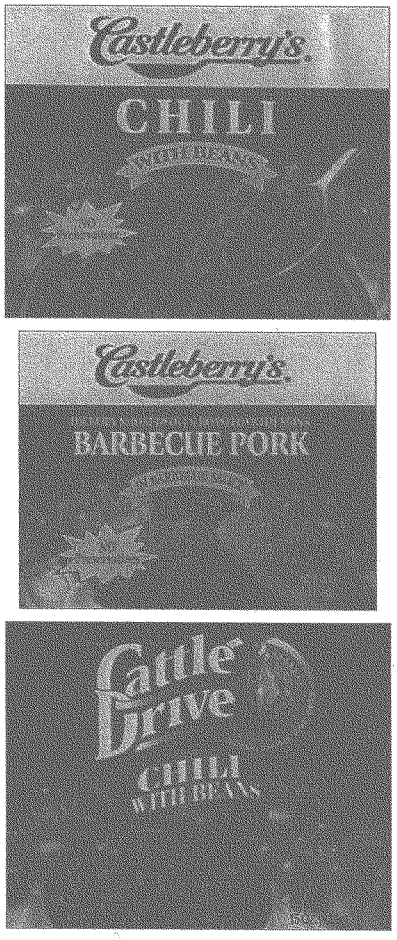
#

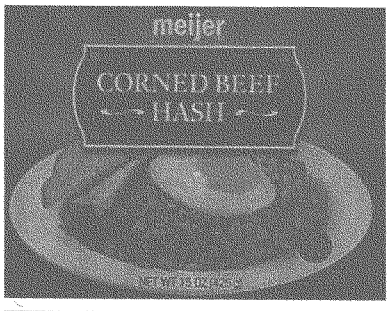
www.fsis.usda.gov

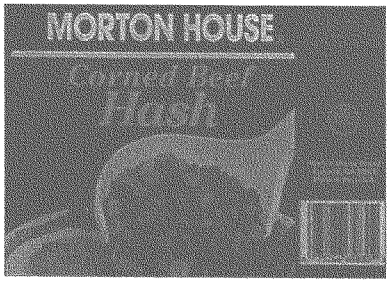
Food Safety Questions? Ask Karen!
FSIS' automated response system can provide food safety information 24/7

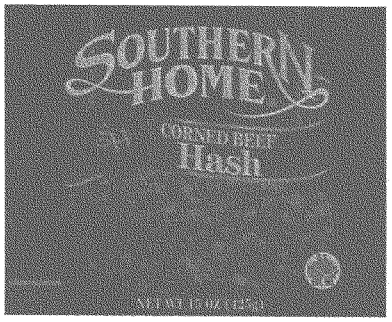
Last Modified: July 19, 2007

Product Labels


Castleberry's
CHILI
Castleberry's
BARBECUE PORK
Cattle Drive
CHILI
WITH BEANS







USDA Recall Classifications	
Class I	This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.
Class II	This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.

Class III	This is a situation where the use of the product will not cause adverse health consequences.

Castleberry's shuts Georgia plant as part of botulism probe

WASHINGTON (AP) — Castleberry's Food has closed its production facility in Augusta, Ga., after 16 cans of chili sauce tested positive over the weekend for the bacteria that causes botulism, company officials said Monday.

In addition, the company has hired an outside firm to visit more than 8,500 retailers around the country in an effort to quickly get recalled products off store shelves.

RECALLED ITEMS: Complete list

So far, four cases of botulism have been reported — two from Indiana and two from Texas. All four people consumed Hot Dog Chili Sauce Original, a product made by Castleberry's.

On Saturday, Castleberry's expanded its voluntary recall of canned meat products. It recalled more than 80 types of canned chili, beef stew, corned beef hash and other meat products in addition to the 10 brands it had recalled Thursday.

Company officials said they were working closely with the Food and Drug Administration and the Department of Agriculture to determine just how widespread the problem is, but they could not provide information about what quantity of the products in question are still on store shelves.

"So that we can devote all available resources to this investigation, we agreed to shut down our entire facility in Augusta. We will not process any more food there until the FDA and the USDA agrees it is appropriate to reopen," said Dave Melbourne, senior vice president for Castleberry's. "And, we have stopped all further product distribution from our centers."

Botulism is a rare but serious illness caused by consuming foods with the botulinim toxin, a nerve toxin that can cause paralysis of the arms, breathing muscles and legs. Symptoms, such as blurred vision and slurred speech, generally begin 18 to 36 hours after eating a contaminated food.

Typically, commercially canned foods are heated long enough and to high enough temperatures to kill the spores. Melbourne confirmed that the botulism occurred in the chili sauce because the product was undercooked.

Out of caution, the company decided to recall all other products produced on that particular production line regardless of the best-use date on the can.

"The current tests only indicate botulism toxin for the chili products, but because other products were also canned using the same equipment, we expanded the recall to include all brands that were canned on the same line," Melbourne said.

The company has also asked consumers to dispose of any questionable goods from Castleberry's in doubled plastic bags. Consumers can get full refunds simply by calling the company. The company is not asking consumers to bring product labels into the grocery store so that they can get a refund.

Consumers with questions about the recall may contact Castleberry's at 1-888-203-8446.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Castleberry's Expands Voluntary Recall of Hot Dog Chili Sauce and Canned Meat Products

Contact:
Doug McGraw, Fleishman-Hillard
(212) 453-2202

FOR IMMEDIATE RELEASE --AUGUSTA, Ga. – July 21, 2007 – Castleberry's Food Company today announced that it is taking extra steps to ensure public safety by voluntarily expanding its recall originally announced on July 18 due to the risk ofbotulinum toxin, a bacterium which can cause botulism.

Botulism can cause the following symptoms: general weakness, dizziness, double-vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these problems should seek immediate medical attention.

The recall originally announced on July 18 affected only 10 products with 'best by' dates from APR30 2009 through MAY22 2009. The extended recall now includes the following canned products in the following sizes with all 'best by' and code dates:

- Austex Onion Hot Dog Chili Sauce, 10 oz can (UPC 3030097101)
- Austex Hot Dog Chili Sauce, 10 oz can (UPC 3030099533)
- Austex Beef Stew, 15 oz can (UPC 3030090815)
- Austex Chili With Beans, 15 oz can (UPC 3030091015)
- Austex Chili With Beans, 19 oz can (UPC 3030092519)
- Austex Chili No Beans, 15 oz can (UPC 3030097715)
- Austex Chili No Beans, 19 oz can (UPC 3030097719)
- Best Yet Corned Beef Hash, 15 oz can (UPC 4217841082)
- Best Yet Chili With Beans, 15 oz can (UPC 4218740842)
- Big Y Chili No Beans, 15 oz can (UPC 1889480424)
- Big Y Corned Beef Hash, 15 oz can (UPC 1889480225)
- Big Y Chili With Beans, 15 oz can (UPC 1889480425)
- Black Rock Chili With Beans, 15 oz can (UPC 3030001715)
- Bloom Hot Dog Chili Sauce, 10 oz can (UPC 2543992448)
- Bryan Hot Dog Chili Sauce With Beef, 10 oz can (UPC 5340030010)
- Bryan Corned Beef Hash, 15 oz can (UPC 5340030110)
- Bryan Chili No Beans, 15 oz can (UPC 5340030200)
- Bryan Chili With Beans, 15 oz can (UPC 5340030205)
- Bryan Chili No Beans, 10 oz can (UPC 5340035264)
- Bunker Hill Hot Dog Chili Sauce, 10 oz can (UPC 7526604152)
- Bunker Hill Chili No Beans, 10 oz can (UPC 7526604112)
- Bunker Hill Spicier Chili No Beans, 10 oz can (UPC 7526604224)
- Castleberry's Hot Dog Chili Sauce, 10 oz can (UPC 3030000101)
- Castleberry's Onion Hot Dog Chili Sauce, 10 oz can (UPC 3030007101)
- Castleberry's Brunswick Stew Chicken & Beef, 15 oz can (UPC 3030000315)
- Castleberry's Barbecue Pork, 10 oz can (UPC 3030000402)
- Castleberry's Barbecue Pork, 14.5 oz can (UPC 3030000415)
- Castleberry's Barbecue Beef, 10 oz can (UPC 3030000602)
- Castleberry's Beef Stew, 15 oz can (UPC 3030000815)
- Castleberry's Corned Beef Hash, 15 oz can (UPC 3030000915)

- Castleberry's Chili With Beans, 15 oz can (UPC 3030001015)
- Castleberry's Sausage Gravy, 10 oz can (UPC 3030005130)
- Castleberry's Creamed Chip Beef Gravy, 10 oz can (UPC 3030005150)
- Castleberry's Hot Chili With Beans, 15 oz can (UPC 3030007217)
- Castleberry's Chili No Beans, 10 oz can (UPC 3030007701)
- Castleberry's Chili No Beans, 15 oz can (UPC 3030007715)
- Castleberry's Georgia Hash, 15 oz can (UPC 3030000215)
- Cattle Drive Beef Stew, 15 oz can (UPC 3030001530)
- Cattle Drive Chili No Beans, 15 oz can (UPC 3030001520)
- Cattle Drive Chicken Chili With Beans, 15 oz can (UPC 3030001525)
- Cattle Drive Chili With Beans, 15 oz can (UPC 3030001515)
- Firefighters Chicken Chili With Beans, 15 oz can (UPC 7372500413)
- Firefighters Chili With Beans, 15 oz can (UPC 737250041)
- Firefighters Chili No Beans, 15 oz can (UPC 7372500412)
- Food Club Corned Beef Hash, 15 oz can (UPC 3680080204)
- Food Club Chili No Beans, 15 oz can (UPC 3680080404)
- Food Club Chili With Beans, 15 oz can (UPC 3680080504)
- Food Lion Hot Dog Chili Sauce, 10 oz can (UPC 3582606911)
- Goldstar Original Chili, 10oz can (UPC 2457500001)
- Goldstar Chili, 15oz can (UPC 2457500005)
- Goldstar Tex-Mex Chili With Beans, 15 oz can (UPC 2457500008)
- Great Value Chili With Beans, 15 oz can (UPC 8113179994)
- Great Value Hot Chili With Beans, 15 oz can (UPC 8113179995)
- Kroger Hot Dog Chili Sauce, 10 oz can (UPC 1111083942)
- Kroger Beef Stew, 15oz can (UPC 1111083928)
- Kroger Chili With Beans, 15 oz can (UPC 1111083930)
- Kroger Chili No Beans, 15 oz can (UPC 1111083908)
- Lowes Foods Chili No Beans, 15 oz can (UPC 4164301092)
- Lowes Foods Corned Beef Hash, 15 oz can (UPC 4164301094)
- Lowes Foods Chili With Beans, 15 oz can (UPC 4164301097)
- Meijer Hot Dog Chili Sauce, 10 oz can (UPC 4125085862)
- Meijer Chili No Beans, 15 oz can (UPC 4125095220)
- Meijer Chili With Beans, 15 oz can (UPC 4125095221)
- Meijer Corned Beef Hash, 15 oz can (UPC 4125095229)
- Morton House Chili With Beans, 15 oz can (UPC 7526665829)
- Morton House Corned Beef Hash, 15 oz can (UPC 7526665830)
- Morton House Chili With Beans, 15 oz can (UPC 7526665993)
- Paramount Hot Dog Chili Sauce, 10 oz can (UPC 7526600510)
- Paramount Chili for Hot Dogs, 15 oz can (UPC 7526600526)
- Paramount Chili No Beans, 15 oz can (UPC 7526600731)
- Paramount Chili With Beans, 15 oz can (UPC 7526600732)
- Piggly Wiggly Chili With Beans, 15 oz can (UPC 4129037252)
- Piggly Wiggly Chili No Beans, 15 oz can (UPC 4129037354)
- Piggly Wiggly Chili No Beans, 10 oz can (UPC 4129037355)
- Piggly Wiggly Corned Beef Hash, 15 oz can (UPC 4129037357)
- Prudence Corned Beef Hash, 15 oz can (UPC 4114100015)
- Southern Home Chili No Beans, 10 oz can (UPC 3825948713)
- Southern Home Chili No Beans, 15 oz can (UPC 0788015340)
- Southern Home Chili With Beans, 15 oz can (UPC 0788015341)
- Southern Home Corned Beef Hash, 15 oz can (UPC 0788015359)
- Steak n Shake Chili With Beans, 10 oz can (UPC 5184400120)
- Thrifty Maid Hot Dog Chili Sauce, 10 oz can (UPC 2114021367)
- Thrifty Maid Chili With Beans, 15 oz can (2114021370)
- Thrifty Maid Corned Beef Hash, 15 oz can (2114021375)
- Triple Bar Ranch Chili With Beans, 15 oz can (UPC 3030005801)
- Triple Bar Ranch Chili With Beans, 15 oz can (UPC 3030005804)
- Triple Bar Ranch Chili No Beans, 15 oz can (UPC 3030005805)
- Value Time Beef and Chicken Chili With Beans, 15 oz can (UPC 1122542159)

In addition, the following canned Natural Balance brand pet food products, which Castleberry's co-packs for Natural Balance, are being recalled. These include:

- Natural Balance Eatables for Dogs Irish Stew With Beef, Potatoes & Carrots, 15 oz can (UPC 2363359860)
- Natural Balance Eatables for Dogs Chinese Take Out With Sauce With Vegetables and Chicken, 15 oz can (UPC 2363359861)
- Natural Balance Eatables for Dogs HOBO Chili With Chicken & Pasta, 15 oz can (UPC 2363359863)
- Natural Balance Eatables for Dogs Southern Style Dumplings With Chicken & Vegetables, 15 oz can (UPC 2363359862)

Consumers should not use these products even if they do not look or smell spoiled. Consumers with these products should dispose of them by double bagging in plastic bags that are tightly closed before being placed in a trash receptacle for non-recyclable trash outside of the home, according to the Food and Drug Administration. Additional instructions for safe disposal can be found at www.cdc.gov/botulism/botulism_faq.htm.

"There is nothing more important to us than the health of those who use our products every day," said Steve Mavity, SVP Technical Services/Quality Assurance for Castleberry's. "We are taking every step necessary, and are working hand in hand with health officials around the clock to ensure the safety of consumers."

Mavity said, "We believe we have isolated the issue to a situation of under-processing on one line of our production facility. As an extra precaution to the recall we announced on Wednesday, we have shut down this line altogether and are recalling all products produced on it."

Castleberry's is working with the U.S. Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Centers for Disease Control and Prevention (CDC) to investigate possible contamination of these products.

Castleberry's was notified by the FDA of two confirmed botulism cases and two potential botulism cases involving individuals who ate Hot Dog Chili Sauce products. No new cases have been reported since the recall was announced on July 18.

There have been no reported illnesses linked to Natural Balance canned pet food, but Castleberry's recommends that all these products should be discarded. While botulism can affect some pets, dogs and cats are inherently resistant. The disease has only been seen occasionally in dogs and has not been reported in cats. Ferrets are highly susceptible to botulinum toxin. The incubation period can be two hours to two weeks; in most cases, the symptoms appear after 12 to 24 hours. Botulism is characterized by progressive motor paralysis. Typical clinical signs may include muscle paralysis, difficulty breathing, chewing and swallowing, visual disturbances and generalized weakness may also occur. Death usually results from paralysis of the respiratory or cardiac muscles. Pet owners who have used these products and whose pets have these symptoms should contact their veterinarian immediately.

Consumers with any questions should visit Castleberry's Web site (www.castleberrys.com). A toll-free hotline is also available for consumer questions at 1-800-203-4412 or 1-888-203-8446.

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FDA News

FOR IMMEDIATE RELEASE
July 21, 2007

Media Inquiries:
Kimberly Rawlings
Michael Herndon
301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Expands Its Nationwide Warning About the Risk of Botulism Poisoning From Certain Castleberry's Food Products and Dog Food

This press release translated:
En Español | Japanese | Korean | Chinese | Vietnamese | Russian | German

This press release was revised on July 23, 2007, to update the "best by" dates in the fourth paragraph.
This press release was revised on July 26, 2007 to update disposal instructions in the seventh paragraph.

The U.S. Food and Drug Administration is expanding its July 18 warning to consumers. This expansion is for consumers and pet owners regarding canned food products and dog food produced by Castleberry's Food Company of Augusta, Ga., due to the risk of botulinum toxin. Castleberry's is expanding the recall to include all of the following canned products with all "best by" and code dates, and FDA is warning consumers not to purchase or eat any of the canned products listed in the table below.

Hot Dog Chili Sauces	SIZE	UPC CODES
Castleberry's Austex Onion Hot Dog Chili Sauce	10 OZ	30300-97101
Castleberry's Austex Hot Dog Chili Sauce	10 OZ	30300-99533
Castleberry's Hot Dog Chili Sauce	10 OZ	30300-00101
Castleberry's Onion Hot Dog Chili Sauce	10 OZ	30300-07101
Castleberry's Bunker Hill Hot Dog Chili Sauce	10 OZ	75266-04152
Kroger Hot Dog Chili Sauce	10 OZ	11110-83942
Meijer Hot Dog Chili Sauce	10 OZ	41250-85862
Food Lion Hot Dog Chili Sauce	10 OZ	35826-06911
Bloom Hot Dog Chili Sauce	10 OZ	25439-92448
Thrifty Maid Hot Dog Chili Sauce	10 OZ	21140-21367
Natural Balance Eatables dog food varieties:		
Irish Stew with Beef Dog Food	15 OZ	23633-59860
Chinese Take Out with Sauce with Vegetables and Chicken Dog Food	15 OZ	23633-59861
Southern Style Dumplings with Gravy with Chicken and Vegetables Dog Food	15 OZ	23633-59862
Hobo Chili with Chicken Pasta Dog Food	15 OZ	23633-59863

The agency is expanding its warning based in part on FDA test results and information obtained during a joint FDA and U.S. Department of Agriculture inspection of the Castleberry's facility in Augusta, Ga.

Exposure to botulinum toxin can be fatal and two people in Texas and two people in Indiana remain seriously ill and hospitalized with botulism poisoning associated with eating Castleberry's Hot Dog Chili Sauce.

While the previous recall and the known illnesses are linked to "best by" dates of April 30 to May 22, 2009, the firm has extended the recall to include all products listed irrespective of "best by" date. The firm is cooperating with FDA in the recall of these products and has ceased processing and distribution.

In addition, Castleberry's is recalling other products containing meat, which are regulated by the U.S. Department of Agriculture. USDA is also warning the public not to eat certain brands of Castleberry's products containing meat. The list of these USDA-regulated products can be viewed at this link to the USDA website:

http://www.fsis.usda.gov/News_&_Events/Recall_033_2007_expanded/index.asp

Consumers who have any of these products or any foods made with these products should throw them away immediately. Double bag the cans in plastic bags that are tightly closed then place in a trash receptacle for non-recyclable trash outside of the home. Additional instructions for safe disposal can be found at www.cdc.gov/botulism/botulism_faq.htm.

Retailers that have any of these products are asked to assure that they are removed from use and do not accidentally get reintroduced for sale, service or donation. Do not puncture cans or open them in any way for disposal as this will create a potential health hazard. (More information for retailers and foodservice establishments.)

Symptoms of botulism poisoning in humans can begin from 6 hours to 2 weeks after eating food that contains the toxin. Symptoms may include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, and muscle weakness that moves progressively down the body, affecting the shoulders first then descending to the upper arms, lower arms, thighs, calves, etc. Botulism poisoning can also cause paralysis of the breathing muscles which can result in death unless assistance with breathing (mechanical ventilation) is provided. Individuals who show these symptoms and who may have recently eaten one of the Castleberry's products currently under recall should seek immediate medical attention.

The disease has only been seen occasionally in dogs. Ferrets are highly susceptible to botulinum toxin. The incubation period can be 2 hours to 2 weeks; in most cases, the symptoms appear after 12 to 24 hours. Botulism is characterized by progressive motor paralysis. Typical clinical signs may include muscle paralysis, difficulty breathing, chewing and swallowing, visual disturbances and generalized weakness may also occur. Death usually results from paralysis of the respiratory or cardiac muscles. Pet owners who have used these products and whose pets have these symptoms should contact their veterinarian immediately. At this time we are not aware of pet illnesses associated with these products although we recommend that all these products should be discarded.

Castleberry's recommends consumers with any questions or concerns about this recall should go to Castleberry's website (www.castleberrys.com) or call Castleberry's consumer hotline at 1-800-203-4412 or 1-888-203-8446.

Consumers with questions can call FDA at 1-888-SAFEFOOD.

####

Chili Products (Botulism) Recall Page (Includes complete list of FDA and USDA regulated recalled products)

Message for Retailers and Foodservice Establishments on Removal and Disposal of Recalled Products

RSS Feed for FDA News Releases [what is RSS?]

Get free weekly updates about FDA press releases, recalls, speeches, testimony and more.

News & Events

News Releases

Georgia Firm Expands Recall of Canned Meat Products That May Contain *Clostridium botulinum*

Recall Release
FSIS-RC-033-2007

CLASS I RECALL
HEALTH RISK: HIGH

Congressional and Public Affairs
(202) 720-9113
Laura Reiser

En Español

Editors Note: The recall release was updated on August 2, 2007, to add UPC codes and clarify information for consumers.

WASHINGTON, July 21, 2007 - Castleberry's Food Company, an Augusta, Ga., establishment owned by Bumble Bee Foods, LLC, is voluntarily expanding its July 19 recall of canned meat products that may contain *Clostridium botulinum*, the U.S. Department of Agriculture's Food Safety and Inspection Service announced today.

Related Information from FSIS and FDA

A Message for Retailers and Foodservice Establishments on the Removal and Disposal of Recalled Product Due to Botulism Hazard

The recall is being expanded after information gathered by the Food and Drug Administration (FDA) and FSIS indicated that processing malfunctions at the establishment have existed longer than initially estimated. For that reason, Castleberry's has agreed to recall all of the following products that may still be in commerce, regardless of the "best buy" date stamped on the bottom of the can. Consumers who have any of these products or any foods made with these products should throw them away immediately. Double bag the cans in plastic bags that are tightly closed then place in a trash receptacle for non-recyclable trash outside of the home. Additional instructions for safe disposal can be found at www.cdc.gov/botulism/botulism_faq.htm

The following products are subject to recall:

Label/Product Description	Can Size, Ounces (Oz.)	UPC Code	Other Information
Austex Beef Stew	15	30300 90815	Also Distributed in Multi-Packs
Austex Chili No Beans	15	30300 97715	Also Distributed in Multi-Packs
Austex Chili No Beans	19	30300 97719	Also Distributed in Multi-Packs
Austex Chili with		30300	

Beans	15	91015	
Austex Chili with Beans	19	30300 92519	
Best Yet Chili with Beans	15	42187 40842	
Best Yet Corned Beef Hash	15	42187 41082	
Big Y Chili No Beans	15	18894 80424	
Big Y Chili with Beans	15	18894 80425	
Big Y Corned Beef Hash	15	18894 80225	
Black Rock Chili with Beans	15	30300 01715	
Bryan Chili No Beans	10	53400 35264	Also Distributed in Multi-Packs
Bryan Chili No Beans	15	53400 30200	Also Distributed in Multi-Packs
Bryan Chili with Beans	15	53400 30205	Also Distributed in Multi-Packs
Bryan Corned Beef Hash	15	53400 30110	Also Distributed in Multi-Packs
Bryan Hot Dog Chili Sauce with Beef	10	53400 30010	Also Distributed in Multi-Packs
Bunker Hill Original Chili No Beans	10	75266 04112	
Bunker Hill Spicier Chunky Chili No Beans	10	75266 04224	
Castleberry's BBQ Beef	10	30300 00602	
Castleberry's BBQ Pork	10	30300 00402	
Castleberry's BBQ Pork	14.5	30300 00415	
Castleberry's Beef Stew	15	30300 00815	
Castleberry's Brunswick Beef Stew Chicken & Beef	15	30300 00315	
Castleberry's Chili No Beans	10	30300 07701	
Castleberry's Chili No Beans	15	30300 07715	Also Distributed in Multi-Packs
Castleberry's Chili with Beans	15	30300 01015	
Castleberry's Corned Beef Hash	15	30300 00915	

Castleberry's Creamed Chip Beef Gravy	10	30300 05150	
Castleberry's Georgia Hash	15	30300 00215	
Castleberry's Hot Chili with Beans	15	30300 07217	Also Distributed in Multi-Packs
Castleberry's Sausage Gravy	10	30300 05130	
Cattle Drive Beef Stew	15	30300 01530	
Cattle Drive Chicken Chili with Beans	15	30300 01525	
Cattle Drive Chili No Beans	15	30300 01520	
Cattle Drive Chili with Beans	15	30300 01515	Also Distributed in Multi-Packs
Firefighter Chicken Chili with Beans	15	73725 00413	
Firefighter Chili No Beans	15	73725 00412	
Firefighter Chili with Beans	15	73725 00411	
Food Club Chili No Beans	15	36800 80404	
Food Club Chili with Beans	15	36800 80504	
Food Club Corned Beef Hash	15	36800 80204	
Goldstar Chili	10	24575 00001	
Goldstar Chili	15	24575 00005	
Goldstar Tex Mex Chili with Beans	15	24575 00008	
Great Value Chili with Beans	15	81131 79994	Canada Distribution Only
Great Value Hot Chili with Beans	15	81131 79995	Canada Distribution Only
Kroger Beef Stew	15	11110 83928	
Kroger Chili No Bean	15	11110 83908	
Kroger Chili with Beans	15	11110 83930	
Lowes Chili No Bean	15	41643 01092	
Lowes Chili with Beans	15	41643 01097	
Lowes Corn Beef		41643	

Hash	15	01094	
Meijer Chili No Beans	15	41250 95220	
Meijer Chili with Beans	15	41250 95221	
Meijer Corned Beef Hash	15	41250 95229	
Morton House Chili with Beans Beef And Chicken	15	75266 65851	Also Distributed in Multi-Packs
Morton House Corned Beef Hash	15	75266 65830	
Paramount Chili No Beans	15	75266 00501	
Paramount Chili with Beans	15	75266 00502	
Paramount Hot Dog Chili Sauce	10	75266 00510	
Paramount Hot Dog Chili Sauce	15	75266 00526	
Piggly Wiggly Chili No Beans	10	41290 37355	
Piggly Wiggly Chili No Beans	15	41290 37354	
Piggly Wiggly Chili with Beans	15	41290 37252	
Piggly Wiggly Corned Beef Hash	15	41290 37357	
Prudence Corned Beef Hash	15	41141 00020	Also Distributed in Multi-Packs
Southern Home Chili No Bean	10	38259 48713	
Southern Home Chili No Bean	15	07880 15340	
Southern Home Chili with Beans	15	07880 15341	
Southern Home Corned Beef Hash	15	07880 15360	
Steak N Shake Chili with Beans	10	51844 00120	
Thrifty Maid Chili with Beans	15	21140 21370	
Thrifty Maid Corned Beef Hash	15	21140 21375	
Triple Bar Chili No Beans	15	30300 05805	Also Distributed in Multi-Packs
Triple Bar Chili with Beans	15	30300 05804	Also Distributed in Multi-Packs
Triple Bar Chili with Beans Slow Cooked	15	30300 05801	

Value Time Beef & Chicken Chili with Beans	15	11225 42159	

Each can label or can end bears the establishment number "EST. 195" or "P-650" inside the USDA seal of inspection. The canned meat products were distributed nationwide, with the exception of Great Value chili products which were exported only to Canada. The problem was discovered during an investigation into illnesses in Indiana and Texas. The investigation led to a recall by FDA of three types of meatless hotdog chili sauce. The FDA's recall release can be found at www.fda.gov. That recall is also being expanded to include all meatless products produced at the plant that might still be in commerce.

On July 21, the FDA also issued an expanded recall for the following hot dog chili sauce products and Natural Balance Eatables dog food varieties:

Label/Product Description	Can Size, Ounces (oz.)	UPC Code
Austex Hot Dog Chili Sauce	10	30300 99533
Austex Hot Dog Chili Sauce with Onions	10	30300 97101
Bloom Hot Dog Chili Sauce	10	25439 92448
Bunker Hill Hot Dog Chili Sauce	10	75266 04152
Castleberry's Hot Dog Chili Sauce	10	30300 00101
Castleberry's Hot Dog Chili Sauce with Onions	10	30300 07101
Food Lion Hot Dog Chili Sauce	10	35826 06911
Kroger Hot Dog Chili Sauce	10	11110 83942
Meijer Hot Dog Chili Sauce	10	41250 85862
Thrifty Maid Hot Dog Chili Sauce	10	21140 21367
Irish Stew Natural Balance Eatables for Dogs	15	23633 59860
Chinese Take Out with Sauce with Vegetables & Chicken Natural Balance Eatables for Dogs	15	23633 59861
Southern Style Dumplings with Gravy with Chicken & Vegetables Natural Balance Eatables for Dogs	15	23633 59862
Hobo Chili with Chicken Pasta Natural Balance Eatables for Dogs	15	23633 59863

Botulism is a rare but serious paralytic illness caused by a nerve toxin. Symptoms of botulism include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness. The illness can cause paralysis, respiratory failure and death. Symptoms usually occur from 18 to 36 hours after eating contaminated food. Anyone who is experiencing any of these symptoms should contact a physician.

For additional information about botulism, please visit the Centers for Disease Control and Prevention's Web site at www.cdc.gov/botulism/botulism.htm.

Consumers with questions about the recall should contact company's Consumer Hotline at (888) 203-8446. Media with questions about the recall should contact the company public affairs representative Della Sweetman at (619) 200-0436 or Doug McGraw at (212) 453-2202.

Consumers with food safety questions can "Ask Karen," the FSIS virtual representative available 24 hours a day at AskKaren.gov. The toll-free USDA Meat and Poultry Hotline 1-888-MPHotline (1-888-674-6854) is available in English and Spanish and can be reached from 10 a.m. to 4 p.m. (Eastern Time) Monday through Friday. Recorded food safety messages are available 24 hours a day.

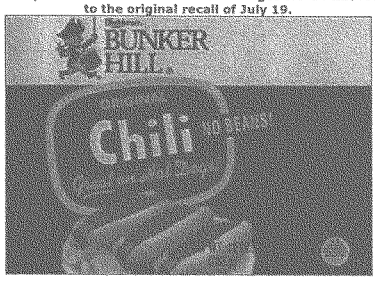
#

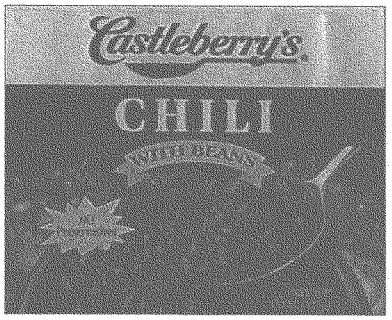
www.fsis.usda.gov

Food Safety Questions? Ask Karen!
FSIS' automated response system can provide food safety information 24/7

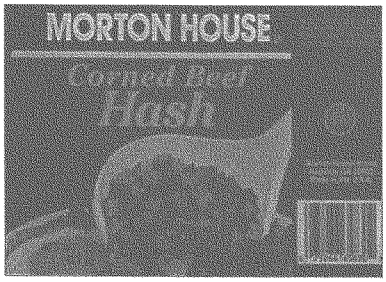
Last Modified: August 15, 2007

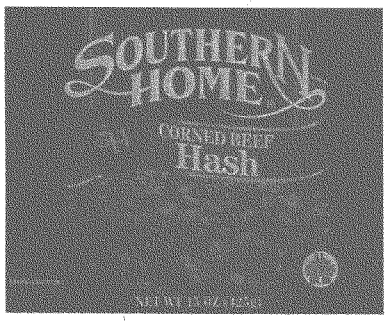
Examples of Product Labels: These images were attached to the original recall of July 19.






Castleberry's
BARBECUE PORK
Cattle Drive
meijer
CORNED BEEF
HASH





USDA Recall Classifications	
Class I	This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.
Class II	This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.
Class III	This is a situation where the use of the product will not cause adverse health consequences.

Establishment Inspection Report	FEI:	**1010894**
Castleberry's Food Company	EI Start:	07/17/2007
Augusta, GA 30901-3929	EI End:	08/10/2007

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SUMMARY

Inspection of this Low Acid Canned Food manufacturer was directed by the FDA Office of Emergency Operations based on 7/17/07 initial findings of Clostridium Botulinum poisoning in two patients in Texas and two patients in Indiana. In Texas, Castleberry's Austex brand Hot Dog Chili Sauce, with a best by date of May 7, 2009, was found in the patient's home and in Indiana, Castleberry's brand Hot Dog Chili Sauce, with a best by date of May 8, 2009, was found along with other brands. ATL-DO immediately assembled a team of investigators to begin a comprehensive investigation.

The investigation and inspection was conducted in accordance with Compliance Program 7303.803A, Domestic Acidified and Low Acid Canned Foods. Previous FDA inspection of this firm on 2/21-23/07 focused on the thirty simulated-meat products manufactured in the area of the firm known as the "kosher room". The 2/21-23/07 inspection was classified VAI and the firm's

management promised corrective action. This firm utilizes vertical still retorts and Malo crateless retorts for manufacturing FDA-regulated product. The focus of this inspection was on the manufacturing of Hot Dog Chili Sauce in the Malo crateless retorts.

On 7/20/07 an FDA-482c, Notice of Inspection-Request for Records, was issued to the firm in order to expedite the delivery of records, and on 7/21/07 an Order for an Emergency Permit was issued to the firm for all FDA-regulated Low Acid Canned Foods made in this facility. Following the issuance of FDA's Order for an Emergency Permit on 7/21/07, the USDA issued a suspension of inspection to the firm on 7/22/07. This suspension encompassed all USDA products made by the firm on all retorting systems.

The FDA investigative team consisted of Robert P. Neligan, ATL-DO Low Acid and Acidified Food Specialist, T. Linda Stewart, ATL-DO Seafood and Food Specialist, Claudette Brooks, ATL-DO Medical Device Specialist, James P. Lewis, Investigator, E. Harold Blackwood, Investigator, and Michael Mignogna, Food Technologist, CFSAN. Accompanying the team during this inspection were Georgia Department of Agriculture Inspectors William C. (Chad) McCord, Darius P. Gresham, Kathleen M. Worthington, Allison S. Strickland, and Thomas R. Rowland.

The inspection was started on the evening of 7/17/07 by T. Linda Stewart, FDA, and William C. (Chad) McCord, GDA. Credentials were presented and FDA forms 482, Notice of Inspection, 482a, Demand for Records, and 482b, Request for Information, were issued to Mr. Dennis J. Donahue, Vice President, Castleberry Food Company. The purpose of the inspection was explained to Mr. Donahue. The focus of this initial meeting centered on Castleberry's Austex brand Hot Dog Chili Sauce with a lot code including "best by May 7, 2009" and Castleberry's brand Hot Dog Chili Sauce with a lot code including "best by May 8, 2009". An inquiry was made into the firm's knowledge of any problems with these production dates. Management responded by stating they had determined post-processing contamination during this timeframe due to can seam problems.

By 7/18/07, information became more evident that Hot Dog Chili Sauce manufactured by Castleberry's was the responsible product in the C. Botulinum poisonings. A review of processing records revealed the Hot Dog Chili Sauce was processed in a single bank of 10 Malo retorts. The FDA team, now including Robert P. Neligan, began requesting records necessary for the investigation. Repeatedly, from 7/18/07 to 7/20/07, the FDA team requested the following records for review: retort maintenance, retort repairs, internal investigations into problems during the spring of 2007, all Malo corporation correspondence, and distribution records. Maintenance records on the Malo retorts would have offered direction at this point in the inspection. However, those maintenance records were stored on the laptop computer of Mr. Kirk Baumann and Mr. Baumann was on vacation. The laptop was in his possession making any attempt to review those records impossible until his arrival back to the firm. On the evening of 7/20/07 the U.S. Food and Drug Administration issued an FDA-482c to the firm which stated, in part, that the firm would have 24 hours to provide the FDA team all of the records requested. It was stated that failure to comply with this request would constitute a prohibited act in accordance with the F,D,& C Act.

Establishment Inspection Report	FEI:	**1010894**
Castleberry's Food Company	EI Start:	07/17/2007
Augusta, GA 30901-3929	EI End:	08/10/2007

On 7/18/07 this firm voluntarily recalled Hot Dog Chili Sauce, with and without onions, under the brands of Castleberry's, Austex, and Kroger's. The recall was limited to production from April 30, 2007 to May 22, 2007. On July 21, the firm expanded this recall to all products manufactured on the Malo 1-10 line for a period of two years.

Expanded recall list:

Hot Dog Chili Sauces	SIZE	UPC CODES
Castleberry's Austex Onion Hot Dog Chili Sauce	10 OZ	30300-97101
Castleberry's Austex Hot Dog Chili Sauce	10 OZ	30300-99533
Castleberry's Hot Dog Chili Sauce	10 OZ	30300-00101
Castleberry's Onion Hot Dog Chili Sauce	10 OZ	30300-07101
Castleberry's Bunker Hill Hot Dog Chili Sauce	10 OZ	75266-04152
Kroger Hot Dog Chili Sauce	10 OZ	11110-83942
Meijer Hot Dog Chili Sauce	10 OZ	41250-85862
Food Lion Hot Dog Chili Sauce	10 OZ	35826-06911
Bloom Hot Dog Chili Sauce	10 OZ	25439-92448
Thrifty Maid Hot Dog Chili Sauce	10 OZ	21140-21367

Natural Balance Eatables dog food varieties:	SIZE	UPC CODES
Irish Stew with Beef Dog Food	15 OZ	23633-59860
Chinese Take Out with Sauce with Vegetables and Chicken Dog Food	15 OZ	23633-59861
Southern Style Dumplings with Gravy with Chicken and Vegetables Dog Food	15 OZ	23633-59862
Hobo Chili with Chicken Pasta Dog Food	15 OZ	23633-59863

Labels for the FDA-regulated products in the expanded recall are included as exhibit 1A – 1N, four identical copies of each label, to this report.

Based on the firm's own findings of Botulinum toxin in their sample of Castleberry's Hot Dog Chili Sauce manufactured on May 8, 2007, with a timestamp of "0224", submitted on 7/19/07 to the Food

Products Association (FPA), and discussions with the FDA, the firm decided on 7/21/07 to voluntarily expand the recall going back for a period of two years. This expanded recall involved 2,230,490 cases of Hot Dog Chili Sauce under various brands and 114,779 cases of Natural Balance pet food.

On the third day of the inspection, records, including but not limited to, quality control reviews of problems in the spring of 2007, outside contractor work orders (specifically Malo personnel work orders), consultant reports of problems for 2007, and outside lab analyses for problem products were unavailable from management. These records were essential to the Investigative team's assessment of the depth and scope of the situation. Finally, on Friday night, July 20, 2007, we met with both Castleberry and Bumble Bee management and some records were made available. Coinciding on this same evening, the U.S. Food and Drug Administration issued an FDA-482c, Notice of Inspection – Request for Records, requiring management to provide specific records.

One record provided to the team on the evening of 7/20/07 was a 42-page report (exhibit 2) from William R. Cole, TechniCal, summarizing his 5/29-31/07 and 6/5-8/07 investigation into swollen cans from the April/May 2007 production. TechniCal is an industry recognized processing authority with a reputation for solving problems in the canning industry. Mr. Cole's investigation was focused on Beef Stew, Chili, Corned Beef Hash, and Hot Dog Chili Sauce. All of these were manufactured in April/May of 2007 and exhibited swells as finished product per FPA laboratory results.

Mr. Cole's opening paragraph in his conclusion on page 30 of this report states "Based upon my review of the FPA/Dublin and FPA/DC laboratory reports, my review of seaming, container cooling operations, and post-process handling operations on the Malo 1 and Vertical steam still retort lines; and conversations with various plant and plant supporting personnel, I believe the cause of the spoilage for all production dates listed was due to post-processing contamination". During this timeframe, Bumble Bee brought in Crown Cork and Seal to review the seamers and can seams, and ChemTreat, Inc. to review the cooling canal sanitizing system. On 6/5/07 a two-page report was issued from Crown Cork and Seal showing that four hard swells and six control cans of beef stew were analyzed with the conclusion the swells were attributable to post process contamination (exhibit 3, 3-pages). ChemTreat issued a final report on 6/19/07, and even though it does not specifically state post-processing contamination was occurring, it cites deficiencies in the firm's cooling canals which can be a contributing factor in post-process contamination (exhibit 4; 2-pages). There is evidence the firm was having some post-processing issues during this timeframe. It is also evident that the firm accepted post-processing as the reason for the swollen cans and did not investigate the issue further into other possible sources. This investigation revealed, due to malfunctioning equipment, that under-processing was also occurring during this timeframe.

Because of the information provided by the three consultants, Castleberry management determined they had a post-processing contamination problem. The laboratory results from both Food Products Association (FPA) labs in Dublin, CA and Washington D.C. showed mesophilic, anaerobic, spore

forming bacteria in many of the swollen cans but FPA repeatedly stated the cause of spoilage as unknown (exhibit 5; 30 pages including a two-page summary of all samples submitted by this firm from May 16, 2007 to July 31, 2007). Only the May 30, 2007 FPA results for Canned Beef Stew made on April 19, 2007 identifies post-processing spoilage as the cause.

On 7/19/07 a team of FDA Investigators including Christopher Wilcox, Derek Price, Aaron Wozniak, and Harold Blackwood were sent to the firm's warehouse located at 1425 Lovers Lane. The eight days of Hot Dog Chili Sauce made by Castleberry's from April 30 to May 22, 2007 were on QC hold in this warehouse. It was observed that Castleberry personnel had sorted through the lots and destroyed most of the swollen cans prior to our visit. Field examinations were conducted on the lots and samples were collected.

During this inspection the U.S. Food and Drug Administration collected samples of Castleberry's Austex and Castleberry's brand Hot Dog Chili Sauce with the "best by May 7, 2009" and "best by May 8, 2009" lot codes. Documentary samples, with accompanying affidavits, were collected to establish interstate commerce (exhibit 6A-B; affidavits).

- FDA sample 428113, collected 7/18/07, consisting of 17 swollen cans and 12 control cans, found C. Botulinum toxin in 16 of 17 swollen cans. This sample included the same timestamp and lot code from the May 8, 2007 production as the can found in the Indiana home.
- FDA sample 420352, collected on 7/19/07, consisting of 96 cans, six of which were swollen. This also was a sample of the May 8, 2007 production. Four of the six swollen cans were positive for C. Botulinum toxin.
- FDA sample 420353, collected on 7/19/07, consisting of 96 cans, one of which was swollen. This was a sample of the May 7, 2007 production. This swollen can was found to be positive for C. Botulinum toxin.

In summary, the scope of this inspection was two-fold: first, in implementing a rapid recall of all products potentially contaminated with C. Botulinum toxin from the market place; and secondly, a complex, forensic assessment of what occurred with the Malo retorts to create this situation.

At the conclusion of the inspection an FDA-483, Inspectional Observations, was issued to Mr. James T. Waits in the presence of the firm's attorney, Ms. Jolyda O. Swaim, from Olsson, Frank, and Weeda law firm. The FDA-483 focused on those items that significantly contributed to this firm's manufacture of finished products contaminated with Clostridium Botulinum toxin. An open discussion was held on each objectionable condition.

On 8/14/07 the law firm of Olsson, Frank, and Weeda submitted a limited objection to the Order requiring Emergency Permit. Discussions are on-going between Castleberry and the FDA.

Establishment Inspection Report	FEI:	**1010894**
Castleberry's Food Company	EI Start:	07/17/2007
Augusta, GA 30901-3929	EI End:	08/10/2007

ADMINISTRATIVE DATA

Inspected firm:	Castleberry's Food Company
Location:	1621 15th St Augusta, GA 30901-3929
Phone:	706-733-7765
FAX:	
Mailing address:	1621 15th St Augusta, GA 30901-3929
Dates of inspection:	7/17/2007, 7/18/2007, 7/19/2007, 7/20/2007, 7/21/2007, 7/22/2007, 7/24/2007, 7/25/2007, 7/26/2007, 7/27/2007, 7/28/2007, 7/30/2007, 7/31/2007, 8/1/2007, 8/2/2007, 8/3/2007, 8/6/2007, 8/7/2007, 8/8/2007, 8/9/2007, 8/10/2007
Days in the facility:	21
Participants:	Robert P. Neligan, Investigator Claudette D. Brooks, Investigator James P. Lewis, Investigator Theresa L. Stewart, Investigator Ernest H. Blackwood, Investigator Michael S. Mignogna, Investigator

On this inspection credentials were collectively presented to the following individuals prior to the issuance of FDA forms 482, 482a, 482b, and 482c: Mr. Dennis J. Donahue, Vice President; Mr. William (nmi) Conley, QA Manager; Mr. Christopher W. Rial, Distribution Center Manager; and Mr. Lester H. Florence, Business Unit Manager. Credentials were also presented to Mr. Fred Nolte, Director of QA for Bumble Bee Foods, LLC; and Ms. Jolyda Swaim, Attorney from Olsson, Frank & Weeda, Washington, DC .The affidavits associated with Documentary samples 432090 and 432091 were read and signed by Mr. James T. Waits, General Manager.

The following FDA forms were issued on this inspection:

FDA-482, Notice of Inspection; issued to Dennis J. Donahue, Vice President, by T. Linda Stewart, CSO, on 7/17/07.

FDA-482a, Demand for Records, issued to Dennis J. Donahue, Vice President, by T. Linda Stewart, CSO, on 7/17/07.

FDA-482b, Request for Information, issued to Dennis J. Donahue, Vice President, by T. Linda Stewart, CSO, on 7/17/07.

FDA-482, Notice of Inspection, issued to Dennis J. Donahue, Vice President, by Robert P. Neligan, CSO, on 7/18/07.

FDA-482, Notice of Inspection, issued to William (nmi) Conley, QA Manager, by T. Linda Stewart & Robert P. Neligan, CSO's, on 7/18/07 for the Castleberry's 1425 Lovers Lane Warehouse.

FDA-482, Notice of Inspection, issued to William (nmi) Conley, QA Manager, by T. Linda Stewart & Robert P. Neligan, CSO's, on 7/18/07 for the Castleberry's 1414 Hayes Street Warehouse.

FDA-482, Notice of Inspection, issued to Christopher W. Rial, DC Manager, by E. Harold Blackwood, Derek C. Price, Christopher C. Wilcox, and Aaron P. Wozniak, CSO's, on 7/19/07, for the Castleberry's 1425 Lovers Lane Warehouse.

FDA-482, Notice of Inspection, issued to William (nmi) Conley, QA Manager, by Michael S. Mignogna, Food Technologist and Processing Authority, CFSAN, on 7/19/07.

FDA-482c, Notice of Inspection-Request for Records, with accompanying attachment issued to Dennis J. Donahue, Vice President, by Robert P. Neligan & T. Linda Stewart, CSO's, on 7/20/07.

Order Requiring Emergency Permit, issued to Dennis J. Donahue, Vice President, by Robert P. Neligan & T. Linda Stewart, CSO's on 7/21/07.

FDA-482, Notice of Inspection, issued to Lester H. Florence, Business Unit Manager, by James P. Lewis, Claudette D. Brooks, and E. Harold Blackwood, CSO's, on 7/25/07.

FDA-482a, Demand for Records, issued to Lester H. Florence, Business Unit Manager, by James P. Lewis, Robert P. Neligan, Claudette D. Brooks, and E. Harold Blackwood, CSO's, on 7/25/07.

FDA-482b, Request for Information, issued to Lester H. Florence, Business Unit Manager, by James P. Lewis, Robert P. Neligan, Claudette D. Brooks, and E. Harold Blackwood, CSO's, on 7/25/07.

FDA-483, Inspectional Observations, issued to Mr. James T. Waits, General Manager, by Robert P. Neligan, T. Linda Stewart, Claudette D. Brooks, James P. Lewis, E. Harold Blackwood, and Michael S. Mignogna, Investigators on 8/10/07.

FDA-484, Receipt for Samples, issued to James T. Waits, General Manager, by T. Linda Stewart, CSO, on 8/10/07.

FDA-484, Receipt for Samples, issued to James T. Waits, General Manager, by T. Linda Stewart, CSO, on 8/10/07.

As a team inspection, sections of this report were written by the following members: Robert P. Neligan; Summary, Firm's Training, Manufacturing/Design Operations, Manufacturing Codes, Complaints, Recall Procedures, Objectionable Conditions and Management's Response, Refusals, Voluntary Corrections, Exhibits Collected, and Attachments. Claudette D. Brooks: History, Interstate Commerce, Jurisdiction, Individual Responsibility and Persons Interviewed, and General Discussion with Management. James P. Lewis contributed to the introduction of the Manufacturing/Design Operations; and E. Harold Blackwood contributed the Records Reviewed and Samples Collected sections.

Two USDA employees, Tom Roberts and Alex Bentley are the assigned USDA inspectors who are on-site during processing of USDA-regulated products.

HISTORY

Castleberry Food Company was founded in 1926 in Augusta, Georgia on the popularity of its founder's barbecue pork and beef recipes. Today, Castleberry's has grown and has added other products to their line, including barbecue, chilies, and stews. There are two manufacturing sites in Augusta, GA consisting of a large 230,000 sq. foot facility on 22 acres that processes canned products and a 25,000 square foot facility that processes fresh vegetables. Additionally, Castleberry Food Company owns another facility located in Cape May, NJ.

In early 2005, Castleberry's was acquired by Connors Bros. Income Fund. The fund itself is based at 80 Tiverton Ct., Suite 600, Markham, Ontario, L3R 0G4 and is an unincorporated open-ended trust established under the laws of the Province of Ontario, Canada that indirectly holds, through its subsidiaries, a majority position in two operating companies. The operating companies are Clover Leaf Seafoods, L.P. and Bumble Bee Foods, LLC. Together, these two operating companies comprise North America's largest branded seafood company, under the brands of, Bumble Bee®, Brunswick®, Snow's®, Clover Leaf® and Beach Cliff®.

Connor Brothers Income Fund is operated by a Board of Trustees:
Bernard Valcourt, Chairman
Howard Brodie, Chairman Governance Committee
Scott Perekslis, Chairman Compensation Committee

Current Officers:
Christopher Lischewski, President/CEO Connors Brothers Limited
J. Douglas Hines, Executive Vice President, Chief Operating Officer
Kent McNeil, Executive Vice President, Chief Financial Officer

Clover Leaf, based in Toronto, sells canned and refrigerated seafood internationally and operates a sardine factory in Blacks Harbour, New Brunswick. Bumble Bee, based in San Diego, California produces and sells canned seafood and canned protein products in the United States and operates tuna factories in California, Puerto Rico, Trinidad, and Fiji; a shrimp factory in Louisiana; and a sardine factory in Maine. Castleberry Food Company is wholly-owned by Bumble Bee Foods, LLC.

Bumble Bee offers a wide variety of canned chicken and canned meat products in the United States under leading brands including Castleberry's®, Sweet Sue®, and Bryan®.

Bumble Bee Foods, LLC Corporate Officers:
J. Douglas Hines, Executive Vice President, Chief Operating Officer
Maurice W. Callahan, Senior Vice President Operations
Steve Mavity, Senior Vice President Technical Services/Quality Assurance

Key **Bumble Bee** personnel include:
Peter Boudreau, Retired Plant Engineer
Gina Ybanez, QA Manager
Roy Bryant, Senior Vice President Meat and Poultry

Castleberry Food Company currently manufactures shelf-stable protein products, soups, stews, chilies, hashes, sauces, gravies, beans, barbecues and chunk meats. The majority of products are regulated by the USDA; however, a large variety of FDA-regulated vegetarian simulated meat products and meatless hot dog chili sauce are manufactured.

Castleberry key personnel include:

Dennis Donahue, Vice President of Operations
James T. Waits, Vice President/General Manager
Lester Florence, Operations Manager
James Van Ells, QA Director
Kirk Baumann, Maintenance Manager
Merle Clayton, Controller
William C. Thomas, Director of Research & Development
William (nmi) Conley, QA Manager

An organizational chart for the Augusta plant is included as exhibit 7 (10-pages).

Castleberry products are distributed under several product labels, i.e.,

BUNKER HILL®

SWEET SUE ®
MORTON HOUSE ®
CATTLE DRIVE ®
CASTLEBERRY'S ®
BRYAN ®
AUSTEX ®

Products are distributed to either of two local warehouses, a 90,000 square foot warehouse located at 1414 Hayes Drive, Augusta, GA or a 95,000 square foot warehouse located at 1425 Lovers Lane, Augusta, GA. The firm also has several other distribution warehouses including sites in Dayton, NJ; Kent, WA; Buena Park, CA; Honolulu, HI; McDonough, GA; and Romeoville, IL. A list of the warehouses with addresses is attached as exhibit 8 (5-pages).

Castleberry's also owns and operates a 25,000-square foot facility (SPUDS, 1697 Olive Road, Augusta, GA), that processes fresh raw vegetables: crushed beans, dehydrated beans, peeled and diced potatoes and sliced carrots. SPUDS is licensed and routinely inspected by the Georgia Department of Agriculture.

The firm is also licensed with the US Department of Agriculture, Food Safety and Inspection Service, and is assigned Establishment #195 and P650 for chicken processing.

On July 18th, 2007, Castleberry's Food Company voluntarily recalled several FDA-regulated products due to reports that four patients were ill with a diagnosis of Clostridium Botulinum poisoning after consuming Castleberry's products. Chili sauces, chili, barbeque pork and corned beef hash were initially recalled. Subsequently, on July 21st the recall was expanded, for a period of two years of production, to include Natural Balance® Pet Foods and several USDA- regulated products. The assigned recall number is F-000-7.

The firm's routine hours of operation are from 6:00am until 3:30 am, the following morning. The sanitation crew begins work in areas where operations have finished and completes their work around 3:30 am. The schedule is adjusted in accordance with the amount of product scheduled for production. Two USDA employees, Tom Roberts and Alex Bentley are the assigned USDA inspectors who are on-site during processing of USDA-regulated products.

INTERSTATE COMMERCE

According to Merle Clayton, Unit Controller, approximately 8.4% of Castleberry's products are sold in the state of Georgia and 1% may be shipped internationally (Canada and/or Mexico). The remaining products are shipped to one of the warehouses listed in exhibit 8 and distributed within all 50 states.

Establishment Inspection Report	FEI:	**1010894**
Castleberry's Food Company	EI Start:	07/17/2007
Augusta, GA 30901-3929	EI End:	08/10/2007

JURISDICTION

The firm has two on-site USDA inspectors on all shifts. Neither of these inspectors was available during the inspection; however, Dr. John Floyd, USDA territorial manager, was available each day. Additional USDA personnel present during this inspection included:

Andrew Smith, FDIS Staff Officer

Charles J. Sauer, Investigator

Pedro A. Bobea, Senior Compliance Investigator

Paul M. Uhler, Food Technologist

These individuals performed an inspection into processing conditions of USDA-regulated products.

The firm is also inspected by the Georgia Department of Agriculture. The following GDA inspectors participated in the FDA investigation and record review:

William C. McCord, Agriculture Sanitarian

Allison S. Strickland, Agriculture Sanitarian

Kathleen M. Worthington, Agriculture Sanitarian

Thomas R. Rowland, Agriculture Sanitarian

Darius P. Gresham, Agriculture Sanitarian

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Upon arrival at the firm on 7/17/07, Investigator T. Linda Stewart presented credentials and the following forms were issued to Mr. Dennis (Denny) J. Donahue, VP of Operations for Cape May and Augusta: FDA-482, Notice of Inspection; FDA-482a, Demand for Records, and FDA-482b, Request for Information . Additionally, the FDA Resource Document and FOI sheet were issued Mr. Donahue; and the ALERT card was provided and explained to him and William (nmi) Conley, QA Manager. Investigator Stewart was accompanied by William C. McCord, Georgia Department of Agriculture, Sanitarian, Consumer Protection Field Forces. On 7/18/07, Investigator Robert P. Neligan, ATL-DO LACF Specialist, joined the inspection and assumed the role of Lead Investigator. Investigator Neligan was on another assignment and unable to join the inspection on 7/17/07. Credentials were presented and the FDA-482, Notice of Inspection, was issued to Dennis J. Donahue, Vice President.

On 7/18/07, Robert P. Neligan and T. Linda Stewart issued an FDA-482, Notices of Inspection, to William Conley, QA Manager, for the two off-site warehouses; namely Castleberry's Food

Company, 1425 Lovers Lane, Augusta, GA 30901 and Castleberry's Food Company, 1414 Hayes St., Augusta, GA 30901.

On 7/19/07 Investigators E. Harold Blackwood, Derek C. Price, Christopher C. Wilcox, and Aaron P. Wozniak issued the FDA-482 to Mr. Christopher W. Rial, DC Manager Bumble Bee Foods, LLC; 1425 Lover's Lane, Augusta, GA 30901. These CSO's did not participate in the ongoing inspection; instead, they only worked at the Lovers Lane warehouse facility on 7/1907.

On 7/19/07 Michael S. Mignogna, Food Technologist/P.A. presented credentials and issued the FDA-482, Notice of Inspection, to William (nmi) Conley, QA Manager.

On 7/20/07, Investigators Neligan and Stewart presented their credentials and issued FDA Form-482c, Notice of Inspection - Request for Records with the attachment, to Dennis J. Donahue, Vice President. Additionally, an Order Requiring Emergency Permit was sent from FDA General Counsel to Mr. Donahue on 7/21/07.

On 7/25/07 Investigators James P. Lewis, Claudette D. Brooks, and E. Harold Blackwood presented credentials and issued the FDA- Form 482, FDA- Form 482a and FDA- Form 482b to Lester H. Florence, Business Unit Manager. Credentials were also presented to Mr. Fred Nolte, Director of QA for Bumble Bee Foods, LLC; William Conley, Quality Assurance Manager, Castleberry's Food Company; and Jolyda Swaim, Attorney from Olsson, Frank & Weeda, Washington, DC . Mr. Nolte was present from the Vancouver, Canada office.

James T. Waits, General Manager/Vice President joined the firm's management staff on 7/26/07. He stated he is responsible for the entire facility. Investigator Stewart presented an affidavit attesting to the production, shipping, and distribution of the May 7 and May 8, 2007 lots of Castleberry's chili sauce to firm's management. Mr. Waits demonstrated his authority by reading and signing the affidavit in the presence of the firm's legal counsel. Mr. Waits stated he directly reports to Maurice Callahan, Executive Vice President of Operations for Bumblebee. At the close of the inspection the FDA-483, Inspectional Observations, was issued to and accepted by him.

Fred Nolte, Corporate Processing Authority, was present during most of the inspection; however he left the inspection on 7/31/07 due to personal issues. Mr. Nolte has performed the duties of processing authority and director of quality assurance for Connors Bros., which includes oversight of Castleberry's.

Roger Gibb, a former Bumble Bee employee was at the firm in the capacity of an independent consultant. Mr. Gibb stated he retired two years ago. Mr. Gibb held the position of Senior Vice President of Technical Services and Quality Assurance before Steve Mavity assumed the role.

Dennis J. Donahue, VP Operations for Cape May and Augusta was identified as the most responsible person at the firm on a day-to-day basis. He initially received the Notice of Inspection as well as the Order Requiring Emergency Permit.

Lester Florence, Business Unit Manager, of Kosher Products stated he has been employed at this site for 23 years and in his current position for the past 24 months. He stated as manager of kosher

production, he ensures that Kellogg's standards are met and he works with the sales staff. Mr. Florence directly supervises two managers in the kosher production area. He previously reported to Dennis Donahue; however, since Mr. Waits assumed the GM position, he now reports to Mr. Waits.

Wallace Cohen, Business Unit Manager, of the Red Meat Line (Verticals and Malo's) stated he has been employed at this site for approximately 27 years. He is responsible for everything that goes on during production on the vertical and Malo lines. Two supervisors report to him. He stated he previously reported to Dennis Donahue but now reports to James Waits.

Mr. Steven Dabbs, in-house Processing Authority, has been employed at this site for approximately 30 years. He is the primary processing authority for the firm; reportedly however, he has only recently returned to work due to a serious health issue that has kept him from the firm for several months. He was present for several days during the week of 7/30/07 but was not available during the final week of inspection.

James Van Ells, QA Director, was hired during the current inspection. He stated he is responsible for product quality including weight control and product conformance to customer specifications, food safety plans, recall plans, HACCP and food safety training. He has dotted line responsibility to both Steve Mavity and James Waits.

William Conley, QA Manager, stated he is responsible for in-plant quality assurance, retention and holds, as well as product release. He reports to James Van Ells.

Michael K. Duggan, HACCP Coordinator, stated he is responsible for the review of processing records, including HACCP records, and is responsible for getting corrective action for HACCP violations. He also maintains domestic origin records for government bids. He has been employed at this site for 7 years and in his current position for 1 ½ years. He reports to William Conley. Mr. Duggan provided information to the investigators on production records, product specifications, general production information, hold procedures, and employee practices.

Kirk Baumann, Maintenance Manager, has worked at this firm for approximately 15 months. He stated he is responsible for all of the equipment maintenance and in March he instituted a new preventive maintenance program called the INFOR program. He stated previously he reported to the plant engineer, Steve Berkebile. He now reports to Mr. James Waits.

Chris Rial, Warehouse Manager, stated he has been employed at the Hayes Street warehouse since May 2005. He is responsible for warehousing activities to include shipping and receiving. He reports to Jill Donahue in the corporate office.

Several key individuals from Bumble Bee, Castleberry's, and outside organizations participated in this inspection. A list of those participants is attached as exhibit 9.

Correspondence from the Agency to the firm should be directed to Mr. James T. Waits, Vice President/General Manager with copies to Mr. James Van Ells, Quality Assurance Director @ 1621 Fifteenth Street, Augusta, GA 30901 and Mr. Steve Mavity, Senior VP of Technical Services QA @ Bumble Bee LLC, P.O. Box 85362, San Diego, CA 92186. The corporate address is 9655 Granite Ridge Drive, Suite 100, San Diego, CA 92123-2697 (858) 715-4000 Ext. 3005.

FIRM'S TRAINING PROGRAM

Eleven members of this firm had completed a Better Process Control School prior to this inspection. This primarily involved the managers and supervisors in Quality Control. On 8/21/07, as one of the post-inspection corrective actions, this firm held an in-house Better Process Control School for 35 employees.

The hourly employees generally receive on-the-job training.

MANUFACTURING/DESIGN OPERATIONS

This firm is a manufacturer of low acid canned foods regulated under dual authority by both US FDA and USDA. In addition, the Georgia Department of Agriculture inspects the firm on a quarterly basis. The firm has private audits from its larger customers, undergoes an annual American Institute of Baking (AIB) inspection, and is regulated by OSHA. This firm has on-site USDA inspectors on all shifts.

The firm has three retort operating systems consisting of crateless steam retorts, vertical still steam retorts and horizontal water spray retorts. The crateless retorts are manufactured by Malo; the majority of the vertical retorts are manufactured by A.K. Robins; the horizontal retorts are manufactured by Surdry. Only USDA regulated products are processed in the two Surdry retorts. Both FDA and USDA products are processed in the crateless and vertical retorts. The firm can be divided into three retorting sections: the front vertical still retorts, the Malo retorts, and the kosher room (exhibit 10; 2-page plant diagram). The kosher room manufactures 30 different simulated-meat products under a contract with the Kellogg Corporation. The Kellogg brands are Loma Linda and Worthington (exhibit 11; product listing). The kosher room has its own kitchen, coolers, processing equipment, seamers, and 14 vertical still retorts. All of the vegetarian products manufactured in the kosher room are hand-filled into the cans. There are 81 vertical retorts in the front room where both FDA and USDA products are processed. There are two Malo lines with the first line known as the Red Meat Line (Malo's 1-10) used in processing both FDA and USDA products, and the second line known as the Chicken Line (Malo's 11-16), used in processing only USDA products.

CRATELESS STEAM RETORTS (MALO RED MEAT LINE)

The Malo crateless retort system is designed with a conveyor system on top which drops cans into an awaiting retort. The conveyor width establishes limitations in the can sizes used with a particular bank of Malo's. Castleberry's limited the cans going into Malo's 1-10 (red meat line) to 10 oz., and 15 oz., cans. The cans enter through a door in the top of the retort and, after retorting, are discharged through a door in the bottom directly into a cooling canal. Since the cans are "jumble-filled", the retort is filled with cushion water to slow the velocity of the falling cans. After the retort is filled, the doors are closed and venting takes place with a steam spreader located in the top pushing the cushion water into a drain valve located in the bottom. At this point, the retort is a vertical still steam retort with a "jumble-fill" instead of using baskets or crates as seen in traditional vertical still retorts. One significant difference with a Malo versus a traditional vertical still is the control of water and condensate. Malo's utilize water for both cushioning and cooling and valves on these water inlets should be well maintained. The cushion water tank is a closed system continually circulating water for both the cushion phase and cooling phase.

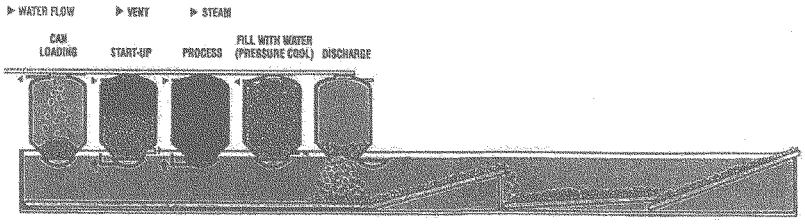
The Malo retort condensate drain is controlled by a valve and opens to drain the condensate if it reaches a critical high level. It also has an alarm/light to indicate when the high level is reached, but does not have a recorder to provide a continuous permanent record of condensate level and drain valve status. The condensate bleeder is constantly open and is installed below the false bottom door to provide visual awareness to the retort operator that there is no condensate buildup in the retort during thermal processing. The false bottom door is used to separate the cans from any condensate that may collect at the very bottom of the retort. After the cushion water is replaced by steam, the cans are cooked, according to the scheduled process, and at the proper temperature/pressure. It is crucial in these retorts for all condensate/water to be discharged prior to the cooking process. After cooking, the retort is again filled with water and pressure cooling is initiated.

After the desired cooling in the retort, the cans are discharged through the bottom door into the cooling water canal for final cooling. The processed cans are conveyed through the discharge end of the canal to a line conveyor, can washer, and then to labeling.

An automated microprocessor control system provides control of the retort functions and maintains records. The mercury-in-glass thermometer is the reference instrument for temperature in retorting and shall be monitored by the retort operator during each cook cycle.

Following is a typical crateless retort processing sequence diagram:

TYPICAL PROCESSING SEQUENCE



The process begins when cans are conveyed from double seamers located in the firm's kitchen through a can wash, an ink jet lot code and timestamp coder, and finally on an overhead conveyor to the bank of 10 Malo retorts, known as the Red Meat Line.

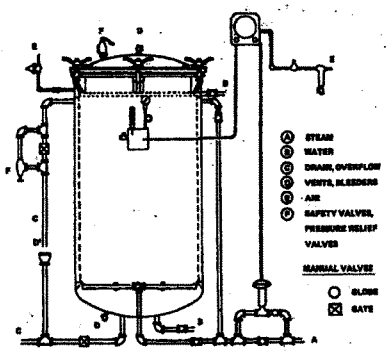
During this inspection, retort operators confirmed the system had override capabilities in which the retort operators could override alarms. These overrides are not monitored in any way within the system through an event log. The high-level sensor in the cushion water tank was not functioning on 7/28/07 and a maintenance employee demonstrated how the sensor could be overridden (even if it had been working) by simply pushing "F4" on the control panel. In addition, the level of water in the site glass for the cushion water tank was located below the retort operator platform and not easily visible to the operator. Upon examination, the water in the tank was above the glass and the exact level of water could not be determined.

VERTICAL STEAM RETORTS (MAJORITY MANUFACTURED BY A. K. ROBINS)

The firm has 65 vertical still retorts located in the front of the building along with 16 more in close proximity known as the "sweet 16". A total of 81 vertical still retorts are available for use in the front area of the facility and all share a common cooling canal. The firm also has 14 identical vertical still retorts in the kosher area. It was observed that the firm has installed two condensate bleeders, coming from the bottom of the retorts, and extending to the workers platform. These condensate bleeders for the vertical stills allow the retort operator to make visual checks on excess condensate.

In vertical still retorts, steam is fed in from the bottom and circulation is achieved through bleeders at the top. Steam spreaders are not necessarily required but good manufacturing practices dictate if a firm installs a spreader, the spreader must be properly maintained. Vertical still retort #65 in the front section and vertical still retorts #1 and #2 in the kosher area were observed to have broken steam spreaders during this inspection.

Following is a typical vertical retort diagram:



In these retorts, venting is critical because steam has much more heating capacity than steam and air combined. Air pockets can insulate the cans and result in under-processing. In this firm, air/water is forced into the retort at the end of the cook to maintain positive pressure during cooling (to minimize can buckling). After the cans have been cooled sufficiently, the retort pressure is reduced.

The vertical retorts in this firm are 41" diameter by 10 ½ feet high and have bottom crate supports. The retorts hold 5 crates (35" diameter by 20" high) and are of proper construction. Divider plates used in the crates meet the required regulations. The retorts are constructed of steel with hinged, counter weighted dome lids.

An FDA-3511A, retort survey for vertical still retorts, was collected on each of the retorting areas in this firm during this inspection (front verticals, kosher room verticals, and the Malo's 1-10). These FDA-3511s are included as attachments to this report. On 8/6/07 team members Robert P. Neligan, Linda Stewart, and James Lewis successfully completed the retort surveys on the Malo retorts and the front vertical still retorts. An attempt to complete the survey on the kosher room retorts was hampered due to excessive steam emanating from the retorts that day. On 8/7/07 these team members were asked by management that no retort survey be conducted on the kosher room retorts due to OSHA safety precautions. In the presence of management, Investigator Neligan placed a call to Mr. James Burn's, SE Region Compliance Officer, Occupational Safety and Health Administration. Mr. Burn's stated that management was correct, without undergoing training to enter a confined space, we were not allowed to collect our measurements for the retort survey on the

kosher retorts. This call was followed by a phone call from Mr. J.T. Brezley, Regional Area Director, OSHA, who further confirmed Mr. Burns' comments. The measurements included in the FDA-3511 for the kosher room were taken by the firm for our benefit since they had the necessary training for confined spaces.

Record Review:

An important accomplishment during this inspection was the review of every processing record for FDA-regulated products from January 1, 2007 to July 20, 2007. FDA Investigators E. Harold Blackwood, and Claudette D. Brooks led this team. Georgia Department of Agriculture sanitarians Allison Strickland, Thomas Rowland, Kathy Worthington, Chad McCord, and Mike Butts assisted.

During the inspection a variety of records were reviewed. These included areas related to incoming raw materials, product preparation, processing records, product hold logs, maintenance records, and shipping and distribution records.

The Malo Daily Retort Processing Records (retort operator's log) for the red meat line (Malo retorts 1-10) were reviewed for the time period January 1, 2007 to July 20, 2007. Included with this record is the corresponding continuous temperature/pressure chart for each retort. All kosher room processing records were reviewed for the time period of January 1 to July 20, 2007 for retorts 1-14. Only FDA-regulated products are processed in these vertical steam retorts. The kosher room review included the retort operator's logs, the puller's record, temperature/pressure continuous chart, and part of the kitchen record (this record showed dry fill testing). In the front section of the building the firm operates 81 vertical still steam retorts that are used for both FDA and USDA products. These processing records were reviewed for the 25 days between January 1, 2007 and July 20, 2007 that FDA-regulated product was processed in these retorts. Also included in the review of the processing records for these vertical retorts were three additional days for each month January 1, 2007 and July 20, 2007. These additional 21 days the firm only processed USDA-regulated products. The Product Hold Log and Finished Product Hold Log were reviewed from January 1, 2007 to July 20, 2007. Michael Duggan, Castleberry HACCP Coordinator, assisted the record review team, providing explanations when needed, and copies of records. Mr. Duggan's primary responsibility is in reviewing processing records for the firm.

Challenges to Malo's #5 and #8:

By comparing processing records to timestamps on FDA samples 428113 and 420352, we were able to determine the production of the product containing C. Botulinum toxin was on Malo #8 and/or #5. No one could definitively verify if the timestamp on the ink-jetting system was set to match the wall clock used by the retort operators and the times recorded on the retort logs. The ink-jetting system

previously was located at the end of the conveyor just prior to the Malo retorts. Management moved the ink-jetting system into the kitchen, locating it just beyond the can wash station after seaming.

With our focus on Malo's 8 and 5, we began a series of challenges to these Malo retorts to see if they could fail. Our first test began on Malo #5. On 7/27/07 a team assembled consisting of Bumble Bee employees; Castleberry employees; FDA investigators James Lewis, Linda Stewart, and Bob Neligan; Dr. John Floyd, USDA; and Ms. Jolyda Swaim, Attorney. This test was video taped by Bumble Bee. A transcript summarizing the test on Malo #5 was provided by Bumble Bee, and reviewed by Bob Neligan, FDA, prior to finalizing (exhibit 12; 3 pages). The cooling water valve on this Malo was taken off and everyone could see the valve had worn a deep groove in the surrounding rubber gasket. This groove prohibited proper seating of the valve. To simulate a normal day of production, this cooling water valve was opened and closed several times. After each successive use, the valve was observed to increase in the leakage amount. By the last test, the valve produced 1700 mL of water in a 60 second period. Clearly, this valve was leaking a substantial amount of water into the bottom of Malo #5. This simulates what could occur during a cook cycle as the work day progressed. If actual cans were in the retort during this challenge this would have increased the amount of water in the bottom of this retort from condensation. Malo #5, with a damaged cooling water valve, was shown to have an excess of water in the bottom of the retort during the test cook cycle on 7/27/07.

During this same test on Malo #5 it was observed the indicator light on the panel was not functioning during the cooling phase of the cooking process. Kirk Baumann, Maintenance Manager, removed the lens, replaced the bulb, secured the lens back in place, and the cooling indicator light illuminated, indicating the process was in the cooling phase. Leaking valves and burned out alarm lights on the control panel provide a picture of the poor maintenance and inattention this firm was giving the Malo retorts.

On Saturday 7/28/07 a similar team of Bumble Bee, Castleberry, FDA, and USDA assembled to begin our series of challenges to Malo #8 (exhibit 13; 2 pages). We began by examining the retort for leaks. No significant leaks were observed before start-up. It was observed that the cushion water bypass drain valve was not functioning. In the event water is leaking into a retort from the cushion water inlet, this valve is designed to expel the water before it could enter the retort.

We then began to operate Malo #8 through its initial steps, including a vent process of pushing the cushion water out of the drain valve, to examine it during a cook cycle. With the drain valves open on Malo's 9 and 10, the venting of Malo #8 created such a backflow of cushion water and steam through the drain line upstream that the entire room filled with steam. The water, still in Malo #8, began to collapse the steam in the vessel causing a loud banging of the pipes. This unexpected result from venting Malo #8 forced Castleberry management to cease the challenge on Malo #8. No further work was accomplished on Malo #8 that day. It did show that under certain circumstances

the venting of one Malo downstream will cause cushion water and steam to flow upstream and enter another Malo when a drain valve is open.

Testing did resume on Malo #8 on 7/30 & 31/07 (exhibit 14; 5 pages). Based on the events of Saturday July 28, we requested that the cushion water tank be overfilled and then vent Malo #8 into the overfilled tank. It should be noted that Malo #8 was only half-filled with cushion water for this test. The purpose of the challenge was to see if venting a Malo into a full cushion water tank would cause water to backflow into an adjacent retort. Again, this created a safety hazard with the cushion water tank bumping and bouncing off the floor. The overflow pea-trap on the cushion water tank did expel water but not a rate sufficient to prevent water from filling the 10" vent pipe on the tank. The design of the vent pipe for the cushion water tank associated with Malo's 1-10 is a horizontal section of pipe approximately 15' with a 90° elbow going straight up to atmosphere above the roof line. A proper design would be a vertical vent from the top of the cushion water tank straight to atmosphere. Even under these stressed conditions on the cushion water tank, Fred Nolte, Bumble Bee, and Bob Neligan, FDA, did not observe any significant amounts of water coming from the opened bottoms of any of the Malo's. However, it was observed that the overflow drain valve on Malo #8 was under so much pressure it opened on its own and remained in a partially opened position for a period of time. This was a result of the pressure being exerted by the overfilled tank. After the system cooled for approximately 15 minutes, the valve returned to the closed position on its own. This overflow drain could be another entry point for water to enter a Malo retort if pressure was being exerted upstream from an overfilled cushion water tank. The retort operators and the maintenance workers both stated they had seen conditions where the cushion water tank had been overfilled and would rumble and jump off the floor.

On 7/30/07 Bumble Bee management brought in John Owens, a local plumber, to thread a fiber optic camera down the drain manifold to see if any blockages in the drain line caused the steam and cushion water to enter Malo's 9 and 10 during the venting of Malo #8 on 7/28/07 (exhibit 15; one page). This was a most unusual occurrence to vent one Malo and have such a back pressure that the cushion water would travel upstream and enter another Malo. Bumble Bee personnel, Castleberry personnel, the FDA team, and Dr. John Floyd, USDA all watched as the fiber optic camera found no blockages. The inside of the cushion water tank, as well as the vent pipe for the tank, were examined with the camera and no blockages were found.

This led the FDA inspection team to examine other conditions on Malo #8 that could have created the under-processing of a limited number of cans. It was observed early on in this inspection that under-processing seemed to occur only on a cluster of 100 cans or more during the cook cycle. Each Malo holds approximately 10,900 cans per cook cycle. FDA sample 428113, with a timestamp of "0223" produced on May 8, 2007, and sample 420352, with a timestamp of "1950" produced on May 7, 2007 were positive for C. Botulinum toxin. Other cans in the samples within 1-2 minutes from the timestamp were negative for the toxin. This narrows the affected cans down to approximately 100 or more cans per retort cook cycle on those days. The seamers used by this firm can operate at a maximum speed of 400 cans per minute. Normal operations would decrease that rate down to 250-300 cans per minute. It still remains viable that a limited amount of water could

cover the bottom layer of cans in a Malo retort causing small clusters of swollen cans. One design flaw noted with Malo's 1-10 was the condensate drain had the condensate bleeder located on the top of a "T" connection. The condensate bleeder could only expel water above the ½" condensate drain pipe. A proper design would place the condensate bleeder on the bottom of the drain pipe, assuring all water from inside the retort and in the condensate drain pipe would be expelled. Another design flaw with Malo's 1-10 was the condensate drain itself was not in view of the retort operators. If a condensate drain was clogged, no one could easily detect this condition. Investigator Neligan recommended to Fred Nolte that each condensate drain pipe be reconfigured to allow a visible check of proper operation.

One critically important event with Malo #8 was the low-pressure reading. A (normal) pressure inside a retort of 15 psig correlates to an operating temperature of 250°. Malo #8 was continually reading a pressure of, on average, 8 psig. This would correlate to an operating temperature of 235°. A list of randomly selected Malo processing logs reveals the following (exhibit 16 A- E):

February 26, 2007 (Malo #8):
Process start @ 12:55; pressure recorded by operator: 7 psig
Process start @ 3:55; pressure recorded by operator: 7 psig

March 19, 2007 (Malo #8):
Process start @ 9:51; pressure recorded by operator: 5 psig

April 24, 2007 (Malo #8):
Process start @ 11:11; pressure recorded by operator: 8 psig
Process start @ 4:48; pressure recorded by operator: 9 psig
Process start @ 9:31; pressure recorded by operator: 9 psig
Process start @ 3:34; pressure recorded by operator: 9 psig

May 7, 2007 (Malo #8):
Process start @ 11:09; pressure recorded by operator: 12 psig
Process start @ 2:46; pressure recorded by operator: 12 psig
Process start @ 6:06; pressure recorded by operator: 10 psig
Process start @ 9:55; pressure recorded by operator: 8 psig
Process start @ 2:19; pressure recorded by operator: 8 psig

May 8, 2007 (Malo #8):
Process start @ 10:10; pressure recorded by operator: 8 psig
Process start @ 2:03; pressure recorded by operator: 10 psig

Process start @ 5:46; pressure recorded by operator: 9 psig
Process start @ 10:20; pressure recorded by operator: 9 psig
Process start @ 2:39; pressure recorded by operator: 9 psig

On February 16, 2007 Malo #8 was taken out of service. Between February 16 & 26, 2007 Malo #8 had a new mother board replaced. The mother board controls and maintains proper function of the retort. On February 26, 2007 Malo #8 was placed back into service. When the firm's management was questioned, no one could identify the events that led to the mother board being replaced and the records prior to February 16 for this retort do not reveal any obvious discrepancies. Beginning on February 26, 2007 when Malo #8 was placed back into service, this retort began showing a measured pressure inside the vessel of, on average, 8 psig. This directly correlates to an operating temperature of 235° F. The Hot Dog Chili Sauce was routinely cooked in the Malo 1-10 retorts at 248° F for 80 minutes with an initial temperature inside the cans of, on average, 160-170° F. The initial temperature of the cushion water inside the vessel was also, on average, 160-170° F.

The recorder chart from February 26 to May 22, 2007 for Malo #8 was reading an average of 248° F. However, a one-page work report, issued by Wayne Brown, Malo Technical Specialist, states on May 30, 2007 the bias on the recording temperature device (RTD) for the Malo #8 recorder chart was found at 124.4. In Wayne Brown's own words in this report he states "I checked the bias and found 124.4. That's far out of line. A high bias is 4." (exhibit 17; one-page report). There are no records to show that management addressed the low pressure readings on Malo #8 from February 26, 2007 until Mr. Brown's visit on May 30, 2007. Malo #8 continued to be operated during this time span.

It can be shown that Malo #8 has an RTD and accompanying chart recorder that were not correctly reading the actual temperature inside the vessel. This same retort consistently shows a pressure of approximately 8 psig which correlates to an operating temperature of 235° F. It is clear there is a problem with Malo #8. The final element of concern is the mercury-in-glass thermometer (MIG). During the timeframe of the low pressure readings in Malo #8, MIG #924 was used on retort #8. On 8/2/07 management was able to locate MIG #924 and a calibration was performed with Bumble Bee personnel, Castleberry personnel, and the FDA present. This calibration revealed MIG #924 was low by 2° (exhibit 18; one-page). Management stated they suspected this MIG had a broken column of mercury. After the calibration test did not reveal a broken column, a propane torch was brought in to run the mercury column to the maximum upper limit of 270°. If a broken column of mercury was located in the stem of the MIG this final test would reveal the broken column. It was observed that MIG #924 did not have a broken column of mercury and was within a reasonable (2°) range.

On each of the cook cycles noted above, the retort operator recorded on his log that the MIG and the recording chart were exactly the same. This was seen consistently in the records for Malo #8. One exception in the above listed records is the May 7th 6:06pm cook cycle where the retort operator listed the MIG at 248° and the recorder chart at 247° F. While one cannot identify anything wrong from just this information, it was found that a retort operator was not reading the MIG or conducting

condensate bleeder checks on Malo #8 during a cook cycle. This was observed on the second day of this inspection. William Conley, QA Manager, and Bob Neligan, FDA, visited the Malo 1-10 line. Seeing that Malo #8 had just finished a cook cycle, Conley and Neligan both went to review the operator's retort log. The retort operator had failed to enter the second check of both the MIG and recorder chart temperatures and failed to enter 4 of the 6 required condensate bleeder checks (exhibit 19; 3 page 7/18/07 retort operator's log). Contribute to this, the 3/26/07 retort log from the kosher room vertical still retorts (exhibit 20; 2 pages). The retort operator's log cites a recording chart temperature of 248° on the third cook cycle for retort 11. The third cook cycle occurred at midnight. The first cook cycle for this retort occurred at noon. The recording chart actually shows the 248° during the first cook cycle at 12:30 pm, not 12:30 am (third cook cycle). This recording chart is printed in real-time as the cook cycles progress through the day. This is not a situation of a pre-printed recording chart being misaligned.

The challenges placed on Malo #8 and #5 revealed that it is possible to have a situation of water in the bottom of a retort during a cook cycle. Malo #8 was operating with a temperature recorder out of bias. Between 2/26/07 and 5/22/07 this retort was showing a pressure in the vessel of, on average, 8 psig which correlates to an operating temperature of 235°. There is evidence of a retort operator not checking the mercury-in-glass or the required condensate bleeder checks on Malo #8. Whether a small cluster of cans had a lower initial temperature than other cans in that cook cycle or, on occasion, water was covering the bottom layer of cans, it can be shown that cans of Hot Dog Chili Sauce did not receive an adequate thermal process. Laboratory results of both the firm's sample and FDA samples found Clostridium Botulinum toxin in small clusters of cans from these retorts.

MANUFACTURING CODES

For FDA-regulated products an example of the lot coding on the cans is as follows:

Top line: "Best by August 10, 2009"
Bottom line: " CA CM2 1234"

Top line explanation: All Castleberry's products are based on that day's production. The "best by" date would be the day of production plus two years. The above example would reflect actual production on August 10, 2007. Please note that a "day's production" does not change when the time stamp extends beyond midnight. A lot code will show a date of production for August 10 and a timestamp of "0223". In actuality, this literally would be 2:23am on the morning of August 11. However, this firm follows a "day's production" for the total length of time associated with the start of production that day.

Bottom line explanation: CA = Castleberry's
CM2 = formula code + production period

1234 = military time stamp

The tray label in casing would have a code of "7222". The first digit is the year followed by the julian date.

For the simulated-meat products manufactured in the firm's kosher room (Kellogg's Loma Linda and Worthington brands) a lot code for the cans is as follows:

Top line: "08107 CS"
Bottom line: "VB 1234"

Top line explanation: 08 = month of production
10 = day of production
7 = year of production
CS = Castleberry co-packer designation

Bottom line explanation: VB = formula code
1234 = military time stamp

COMPLAINTS

There have been no complaints filed from consumers with the U.S. Food and Drug Administration concerning this firm since the last FDA inspection. This inspection was directed by the FDA Office of Emergency Operations based on 7/17/07 initial findings of Clostridium Botulinum poisoning in two patients in Texas and two patients in Indiana.

RECALL PROCEDURES

The firm has established recall procedures in place and performs two mock recalls annually. The firm's recall procedures were demonstrated during this inspection with the 7/21/07 recall of 2,230,490 cases of Hot Dog Chili Sauce under various brands and 114,779 cases of Natural Balance pet food. The recall was based on initial information from the Indiana Department of Health and Texas Department of Health that patients in their states had consumed Castleberry's Hot Dog Chili Sauce prior to the onset of symptoms indicative of Botulinum poisoning.

On 7/18/07, Steve Mavity, Senior VP of Technical Services and Quality Assurance, Bumble Bee LLC, announced the firm was voluntarily recalling Hot Dog Chili Sauce, under the Austex, Kroger, and Castleberry's brands, manufactured from April 30, 2007 to May 22, 2007. On 7/21/07 Mr.

Mavity announced that Bumble Bee was voluntarily expanding the recall to include all FDA-regulated and USDA-regulated products manufactured on the Malo 1-10 line for a period of two years. The significance of the two-year period is all cans receive an ink-jetted lot code that includes a 'best by" date. The expiration date this firm has given their products is 24 months. The expanded recall included all products with "best by" dates from July 21, 2007 to July 21, 2009. Please reference the Summary section of this report for the FDA-regulated products under the expanded recall.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

The system, equipment, and procedures used for thermal processing of foods in hermetically sealed containers were not operated and administered in a manner that ensures commercial sterility is achieved.

Specifically, the firm had cans of Castleberry's Hot Dog Chili Sauce from their May 8, 2007 production analyzed for microbiological contamination by a recognized outside laboratory (FPA). The sample was received by the lab on July 19, 2007 and six cans with a lot code of "Best By May 08 2009 CA CM4 0223" and a timestamp of "0224" were analyzed for Clostridium Botulinum toxin. Four of the hermetically sealed cans in the firms sample were positive for Clostridium Botulinum toxin. Shipping records reviewed on this inspection show this product was released and shipped in interstate commerce.

Reference: 21 CFR 113.40(j)

Supporting Evidence and Relevance:

Based on the following observations, commercial sterility was not achieved for Hot Dog Chili Sauce:

1) FDA sample 428113 collected on 7/18/07 from the firm's warehouse located at 1425 Lovers Lane Augusta, GA 30901 and FDA samples 420352 and 420353 collected on 7/19/07 from the same warehouse were positive for C. Botulinum toxin per ELISA tests and mouse bio-assay.

2) The challenges performed on Malo's #8 and #5 revealed both retorts could produce a small portion of finished product that would not achieve a thermal process sufficient to destroy Clostridium Botulinum spores. This was a result of poor maintenance of the retorts and an overall failure of management to correct ongoing deficiencies in the facility.

FDA Documentary samples 432090 and 432091, dated 8/10/07, document the interstate shipment of the May 7, 2007 and May 8, 2007 production lots associated with the physical samples.

Discussion with Management:

There was no discussion from management or the firm's attorney on this item.

OBSERVATION 2

Each retort did not have an accurate temperature-recording device.

Records show the temperature recorder for Malo #8 was not accurately recording the operating temperature during thermal processes from February 26, 2007 to May 22, 2007. Specifically, a Malo work report issued by Wayne Brown, Malo technician, states on May 30, 2007 the bias on the temperature recorder was at 124.4. This observation is coupled with processing records from February 26, 2007 to May 22, 2007 showing a pressure reading of 7 psi to 9 psi during the cook cycle in Malo #8. A pressure reading of 8 psi correlates to an operating temperature inside the retort of approximately 235 degrees.

Reference: 21 CFR 113.40(a)(2)

Supporting Evidence and Relevance:

Mr. Brown's report (exhibit 17) states the bias on the recorder chart was found at 124.4. His report includes "that's far out of line. A high bias is 4". His report goes on to state "I was asked about the maintenance on the retorts and I told them that two years ago the Malos were maintained very well, but they are maintained poorly now". Exhibit 19, the retort operators log for 7/18/07, shows the retort operator did not check or record the second mercury-in-glass thermometer reading, recording chart reading, and four of the six required condensate bleeder checks for Malo #8 on the first cook cycle.

Discussion with Management:

There was no discussion from management or the firm's attorney on this item.

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OBSERVATION 3

Failure to supply a suitable water valve used for water cooling to prevent leakage of water into the retort during processing.

Specifically, this inspection found the water cooling inlet on Malo #5 was leaking at a rate sufficient to cover cans in the bottom of the retort during a thermal process. Additionally, the cushion water bypass drain valve on Malo #8 was not functioning. This valve is designed to prevent water from entering the retort during a thermal process. It was also noted that the overflow drain valve on Malo #8 would randomly become caught in an open position during the cook phase of operation.

Reference: 21 CFR 113.40(a)(11)

Supporting Evidence and Relevance:

All of the malfunctioning valves described in this observation were observed by Bumble Bee, Castleberry, and FDA personnel.

Discussion with Management:

Investigator Neligan explained the leaking cooling water inlet valve is specific to Malo #5. Mr. Waits explained to Mr. Van Ells the subject testing was performed 7/27/07. Investigator Neligan continued by stating the bypass drain valve is associated with the cushion water inlet on Malo #8 and is designed to prevent cushion water from entering the retort. As the cushion water inlet valve closes, this bypass drain valve, located in front of the inlet valve, should automatically open.

OBSERVATION 4

The condensate bleeder was not checked with sufficient frequency to ensure removal of condensate or equipped with an automatic alarm system for the continuous monitoring of condensate bleeder functioning.

Specifically, the high condensate alarm on Malo #8 was observed to be intermittently non-functioning. On 7/19/07, a stream of water was observed flowing from the condensate bleeder for approximately 5 minutes and the condensate alarm never turned on. In addition, the retort operators stated the high condensate alarm on Malo #8 was often perceived as a false alarm. The reason cited was a mineral build-up on the sensor from hard water used in processing.

Reference: 21 CFR 113.40(c)(5)

Supporting Evidence and Relevance:
Removal of condensate from a Malo retort is critical in assuring cans on the bottom layer during processing are not covered with water. Having condensate alarm lights that intermittently operate is not an acceptable practice. Further, the significance of the alarm is lost when operators state that the retorts are giving false alarms.

Discussion with Management:

It was clarified to management that the reason cited as a mineral build-up causing the false alarms was information reported from the retort operators.

OBSERVATION 5

Required information was not entered on designated forms at the time the observation was made by the retort or processing system operator or designated person.

Specifically, on 7/18/07 it was observed that a retort operator had completed a thermal process cycle on Malo #8 and failed to record the second mercury-in glass and temperature recorder reading. This same Malo #8 cycle showed the retort operator failed to record 4 of the 6 required condensate bleeder checks.

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Castleberry's Food Company	EI Start:	07/17/2007
Augusta, GA 30901-3929	EI End:	08/10/2007

Reference: 21 CFR 113.100(a)

Supporting Evidence and Relevance:

This 7/18/07 retort operators log is provided as exhibit 19 and shows the first cook cycle for Malo #8 does not have the required information.

Discussion with Management:

Management was informed that this shows a retort operator is not reading the mercury-in-glass thermometer during a cook cycle. Mr. Waits, General Manager, inquired if this was due to a lack of training or to negligence. We informed management that this is an example of a lack of supervision and overall failure of proper management.

OBSERVATION 6

Failure to maintain fixtures in repair sufficient to prevent food from becoming adulterated.

Specifically, routine maintenance is needed on the Malo 1-10 line. This was evidenced by a control panel light bulb burned out on Malo #5, valves on Malo's #8 and #5 not working, and the high water fill sensor in the cushion water tank for these Malo's not functioning properly. Also, it was observed that the steam spreaders in the bottom of vertical still retorts #1 and #2 in the kosher room were broken and the spreader in the front vertical #65 was broken.

Reference: 21 CFR 110.35(a)

Supporting Evidence and Relevance:

Wayne Brown, Malo Technical Specialist, states in his May 30 report (exhibit 17) that " two years ago the Malos were maintained very well, but they are maintained poorly now".

Discussion with Management:

We informed management that leaking and inoperative valves, inoperative sensors, control panel lights burned out, and broken steam spreaders are an example of the overall breakdown in management.

OBSERVATION 7

Failure to properly adjust the temperature-recording device. The temperature recorded on the temperature-recording device chart was higher than the mercury-in-glass thermometer during processing.

Specifically, this was observed on 1/3/07, Malo #5, chart reading 271 and MIG reading 254; 1/12/07, Malo #5, chart again reading 10 degrees higher than the MIG; 1/19/07, Malo #6, chart at 251 and MIG reading 248; 6/4/07, Malo #6, chart recorder at 246 and MIG at 236; 6/18/07, Malo #7 & #3, the chart recorder was 3 degrees higher than the MIG; and lastly, 6/29/07, Malo #7, recording chart reading 250 and MIG at 247.

Reference: 21 CFR 113.40(a)(2)

Supporting Evidence and Relevance:

This was observed by the FDA record review team. All processing records from January 1, 2007 to July 21, 2007 were reviewed for all FDA-regulated products manufactured by this firm.

Discussion with Management:
There were no comments from management regarding this observation.

REFUSALS

Repeatedly, from 7/18/07 to 7/20/07, the FDA team requested the following records for review: retort maintenance, retort repairs, internal investigations into problems during the spring of 2007, all Malo corporation correspondence, and distribution records. On the evening of 7/20/07 the U.S. Food and Drug Administration issued an FDA-482c to the firm which stated, in part, that the firm

would have 24 hours to provide the FDA team all of the records requested. It was stated that failure to comply with this request would constitute a prohibited act in accordance with the F,D,& C Act.

GENERAL DISCUSSION WITH MANAGEMENT

At the close of the inspection, the inspection team held a discussion and an exit interview with Messrs. James T. Waits and James Van Ells and Ms. Jolyda O. Swaim, Attorney. An FDA-483, Inspectional Observations, was issued to Mr. Waits and each item was read aloud and discussed with those members of firm's management. Investigator Neligan provided an opportunity for everyone to read the list of deficiencies before beginning the dialogue. He explained the format of the FDA-483 items. The items listed below correspond to those objectionable findings listed on the FDA-483. Management's responses were as follows:

1. No questions/comments from management. All were in agreement with the observation and indicated they understood the issue.

2. Investigator Neligan elaborated on the pressure (Psig) as related to the operating temperatures. No questions/comments from management.

3. Investigator Neligan explained the leaking cooling water inlet valve is specific to Malo #5. Mr. Waits explained to Mr. Van Ells the subject testing was performed on 7/27/07. Investigator Neligan continued by stating the bypass drain valve is associated with the cushion water inlet on Malo #8 and is designed to prevent cushion water from entering the retort. As the cushion inlet valve closes, this bypass drain valve, located in front of the inlet valve, should automatically open.

4. Mr. Waits asked about the statement in Observation #4 on the FDA-483 indicating mineral build-up on an alarm sensor was a result of hard water. He asked how we knew there is "hard water" used in processing. Investigator Neligan stated that is the information he had received from the retort operators. He further stated that we could check the water if necessary. Investigator Neligan stated the focus is on the fact that the alarm is routinely going off. Clarification was requested by management on exactly who cited mineral build-up on the sensor as the reason it would either fail to function or would go off incorrectly. Investigator Neligan stated the retort operators provided that information.

5. Investigator Neligan stated the evidence points to a retort operator not doing his job. Mr. Waits asked whether Investigator Neligan thought the individual was not properly trained or simply did not care about the work. Investigator Neligan responded that malfunction extends from the retort operators through to the retort supervisors. If there are episodes when the work is not done properly, it is an apparent reflection of failure on the entire group. Mr. Van Ells stated accountability starts with management.

6. Investigator Neligan stated routine maintenance is needed on Malo's 1-10. He further stated there is benefit in providing validation information on the retorts to the Agency. Ms Swaim stated the information will be in the response.

7. Management had no comments to Observation #7.

Investigator Blackwood provided a summary of findings during the records review. He recommended the firm adopt a better recordkeeping system as it relates to the retort operators recording the time of day. He suggested the firm use either military time or record 'am' or 'pm' in annotation within the production records.

Investigator Neligan further expounded on the firm's overall neglect of the equipment and the apparent disconnect between the different departments in the company. He stated there was no commitment from the employees in making the products and there was not adequate management oversight. This failure in management was ultimately the reason for the Clostridium Botulinum toxin in the cans.

Mr. Waits stated he has told management they must work together. He spoke of a cultural change necessary within this facility. He stated there will not be any "stand-alone silos".

Investigator Neligan stated management's challenge is to bring the plant into compliance by reestablishing cohesiveness between the departments and pride within the employees. Mr. Van Ells stated they are working on a list of things that need improvement. He stated he plans to begin with proper employee training.

Mr. Waits stated that through the ownership change, Castleberry's lost its identity and so did the employees. He stated he wants to restore pride to their work and what they do. By that same token, he wants employees to realize that Bumble Bee is a resource for Castleberry.

Ms. Swaim stated they will be working to compile information and it will be provided to the Agency in a few days.

SAMPLES COLLECTED

Sample 428113, consisting of 29/10 oz. cans of Castleberry's Hot Dog Chili Sauce Original, with a best by date of May 8, 2009. This sample was collected at the firm's Lover's Lane, Augusta, GA warehouse on July 18, 2007. This sample had 17 cans exhibiting swells, all with a timestamp of "0223". The remaining 12 cans, of timestamps in close proximity of "0223", did not exhibit any swelling and were used as controls. Laboratory results found 16 of the 17 swollen cans were positive for Clostridium Botulinum toxin.

Sample 420351 consisted of 96/10 oz. cans of Castleberry's Hot Dog Chili Sauce Original with a best by date of May 23, 2009. This sample was collected at the firm's Lover's Lane, Augusta, GA warehouse on July 19, 2007. The cans collected were from a partial lot of the May 23, 2007 production run that had been placed on QC Hold for further review. The other portion of the lot had already been shipped to Distribution Centers across the country. A field exam of the portion in the warehouse was conducted with no swollen cans found. Sample was negative for C. Botulinum toxin.

Sample 420352 consisted of 96/10 oz cans of Castleberry's Hot Dog Chili Sauce Original with the best by date of May 08, 2009. This sample was collected at the firm's Lover's Lane, Augusta, GA warehouse on July 19, 2007. This lot was placed on QC Hold and was being culled for swollen cans by the firm when the inspection was started. The culling operation stopped when the Georgia Department of Agriculture placed a Stop-Hold on the warehouse on 7/18/07. The field exam of this lot found six swollen cans. These six cans were part of the 96 cans collected for this sample. The time codes of the six swollen cans were 0223, 0223, 0223, 0224, 1351, and 1735. Laboratory results found four of the six swollen cans positive for Clostridium Botulinum toxin.

Sample 420353 consisted of 96/10 oz cans of Castleberry's Austex Hot Dog Chili Sauce Original with a best by date of May 07, 2009. This sample was collected at the firm's Lover's Lane, Augusta, GA warehouse on July 19, 2007. This lot was on QC Hold and had been culled by the firm for swollen cans on June 2 – 3, 2007. The field exam of this lot found one swollen can which was made part of the 96 cans collected for the sample. The time code of the one swollen can was 1950. Laboratory results found this swollen can was positive for Clostridium Botulinum toxin.

Sample DOC 432090 documents the interstate shipment of Hot Dog Chili Sauce manufactured on May 8, 2007 from Castleberry's Food Company in Augusta, GA. This documentary sample, dated 8/10/07, includes an affidavit that was read and signed by Mr. James T. Waits, General Manager, Castleberry's Food Company.

Sample DOC 432091 documents the interstate shipment of Hot Dog Chili Sauce manufactured on May 7, 2007 from Castleberry's Food Company in Augusta, GA. This documentary sample, dated 8/10/07, also includes an affidavit that was read and signed by Mr. James T. Waits, General Manager.

VOLUNTARY CORRECTIONS

The firm ceased all operations in the plant on 7/19/07. Voluntary corrections were submitted to the FDA by the Attorney's of Olsson, Frank, and Weeda representing Castleberry's Food Company. Those voluntary corrections are under review by the U.S. Food and Drug Administration.

Establishment Inspection Report	FEI:	**1010894**
Castleberry's Food Company	EI Start:	07/17/2007
Augusta, GA 30901-3929	EI End:	08/10/2007

EXHIBITS COLLECTED

Exhibit 1A-N): Labeling for the recalled products manufactured by Castleberry's Food Company of Augusta, GA. There are 14 total product labels with four identical copies of each label provided.

Exhibit 2): The 42-page report, dated 6/14/07, issued by William R. Cole, Director of HACCP Programs and Regulatory Affairs, TechniCal, to this firm concerning the causes of swollen cans manufactured at Castleberry's during April and May, 2007.

Exhibit 3): 3-page memorandum, dated 6/5/07, issued from Rick Koch, Crown Cork and Seal, stating the analysis and conclusion of swollen cans submitted to their Avery Technical Center.

Exhibit 4): 2-page letter, dated 6/19/07, from Thomas E. Sherrill, Area Manager, ChemTreat Chemical Co. stating recommendations for improving the cooling canal systems.

Exhibit 5): 30-page collection of laboratory results from samples submitted by Castleberry's to FPA's labs in CA and Washington D.C. These samples span the time period of the April/May problems at Castleberry's.

Exhibit 6A-B): Affidavits read and signed by James T. Waits, General Manager, for DOC samples 432090 and 432091.

Exhibit 7): 10-page organizational chart for Castleberry's Food Co. in Augusta, GA.

Exhibit 8): 5-page list of Bumble Bee distribution centers located throughout the U.S.

Exhibit 9): Single page list of personnel from Bumble Bee, Castleberry, and others that directly participated in this inspection.

Exhibit 10): 2-page floor diagram of the Castleberry plant showing the area of the front vertical still retorts, the Malo's 1-10, and the kosher room.

Exhibit 11): Single page (double-sided) listing of the Loma Linda and Worthington products manufactured at this facility.

Exhibit 12): 3-page transcript of events during the testing of Malo #5 on 7/27/07.

Exhibit 13): 2-page transcript of events during the testing of Malo #8 on 7/28/07.

Exhibit 14): 5-page transcript of events during the testing of Malo #8 on 7/31/07.

Exhibit 15): Single page transcript of events during the fiber optic testing of the Malo drain lines.

Exhibit 16A-E): 89-pages total of Malo processing records representing one day per month from February 2007 to May 2007. This includes the processing records for May 7 and May 8, 2007.

Exhibit 17): Single page report from Wayne Brown, Malo Technical Specialist, stating the repairs made to the chart recorder for Malo #8. Report dated May 2007.

Exhibit 18): Single page transcript of events during the testing of mercury-in-glass thermometer #924.

Exhibit 19): 3-page Malo processing record for 7/18/07 which shows a failure to include the MIG and recording chart temperature checks on Malo #8/cycle one. This also shows a failure to check the condensate bleeders on Malo #8 (four of six checks missing).

Exhibit 20): 2-page processing record from the vertical still retorts in the kosher room.

Establishment Inspection Report	FEI:	**1010894**
Castleberry's Food Company	EI Start:	07/17/2007
Augusta, GA 30901-3929	EI End:	08/10/2007

ATTACHMENTS

FDA-482, Notice of Inspection; issued by T. Linda Stewart, CSO, on 7/17/07

FDA-482a, Demand for Records, issued by T. Linda Stewart, CSO, on 7/17/07

FDA-482b, Request for Information, issued by T. Linda Stewart, CSO, on 7/17/07

FDA-482, Notice of Inspection, issued by Robert P. Neligan, CSO, on 7/18/07

FDA-482, Notice of Inspection, issued by T. Linda Stewart & Robert P. Neligan, CSO's, on 7/18/07 for the Castleberry's 1425 Lovers Lane Warehouse.

FDA-482, Notice of Inspection, issued by T. Linda Stewart & Robert P. Neligan, CSO's, on 7/18/07 for the Castleberry's 1414 Hayes Street Warehouse.

FDA-482, Notice of Inspection, issued by E. Harold Blackwood, Derek C. Price, Christopher C. Wilcox, and Aaron Wozniak, CSO's, on 7/19/07, for the Castleberry's 1425 Lovers Lane Warehouse.

FDA-482, Notice of Inspection, issued by Michael S. Mignogna, Food Technologist and Processing Authority, CFSAN, on 7/19/07.

FDA-482c, Notice of Inspection-Request for Records, with accompanying issued by Robert P. Neligan & T. Linda Stewart, CSO's, on 7/20/07.

Order Requiring Emergency Permit, issued by Robert P. Neligan & T. Linda Stewart, CSO's on 7/21/07.

FDA-482, Notice of Inspection, issued by James P. Lewis, Claudette D. Brooks, and E. Harold Blackwood, CSO's, on 7/25/07.

FDA-482a, Demand for Records, issued by James P. Lewis, Robert P. Neligan, Claudette D. Brooks, and E. Harold Blackwood, CSO's, on 7/25/07.

FDA-482b, Request for Information, issued by James P. Lewis, Robert P. Neligan, Claudette D. Brooks, and E. Harold Blackwood, CSO's, on 7/25/07.

FDA-483, Inspectional Observations, issued to Mr. James T. Waits, General Manager, by Robert P. Neligan, T. Linda Stewart, Claudette D. Brooks, James P. Lewis, E. Harold Blackwood, and Michael S. Mignogna, Investigators on 8/10/07.

FDA-484, Receipt for Samples, issued by T. Linda Stewart, CSO, on 8/10/07.

FDA-484, Receipt for Samples, issued by T. Linda Stewart, CSO, on 8/10/07.

FDA-3511A, Front vertical still retorts

FDA-3511A, Kosher room vertical still retorts

FDA-3511A, Malo retorts

Establishment Inspection Report	FEI:	**1010894**
Castleberry's Food Company	EI Start:	07/17/2007
Augusta, GA 30901-3929	EI End:	08/10/2007

Robert P. Neligan, Investigator

Claudette D. Brooks, Investigator

James P. Lewis, Investigator

Theresa L. Stewart, Investigator

Ernest H. Blackwood, Investigator

Michael S. Mignogna, Investigator

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202	07/17/2007 - 08/10/2007* FEI NUMBER 1010894

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. James T. Waits, General Manager

FIRM NAME	STREET ADDRESS
Castleberry's Food Company	1621 15th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Augusta, GA 30901-3929	Low Acid Canned Food Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

The system, equipment, and procedures used for thermal processing of foods in hermetically sealed containers were not operated and administered in a manner that ensures commercial sterility is achieved.

Specifically, the firm had cans of Castleberry's Hot Dog Chili Sauce from their May 8, 2007 production analyzed for microbiological contamination by a recognized outside laboratory (FPA). The sample was received by the lab on July 19, 2007 and six cans with a lot code of "Best By May 08 2009 CA CM4 0223" and a timestamp of "0224" were analyzed for Clostridium Botulinum toxin. Four of the hermetically sealed cans in the firms sample were positive for Clostridium Botulinum toxin. Shipping records reviewed on this inspection show this product was released and shipped in interstate commerce.

OBSERVATION 2

Each retort did not have an accurate temperature-recording device.

Records show the temperature recorder for Malo #8 was not accurately recording the operating temperature during thermal processes from February 26, 2007 to May 22, 2007. Specifically, a Malo work report issued by Wayne Brown, Malo technician, states on May 30, 2007 the bias on the temperature recorder was at 124.4. This observation is coupled with processing records from February 26, 2007 to May 22, 2007 showing a pressure reading of 7 psi to 9 psi during the cook cycle in Malo #8. A pressure reading of 8 psi correlates to an operating temperature inside the retort of approximately 235 degrees.

OBSERVATION 3

Failure to supply a suitable water valve used for water cooling to prevent leakage of water into the retort during processing.

Specifically, this inspection found the water cooling inlet on Malo #5 was leaking at a rate sufficient to cover cans in the bottom of the retort during a thermal process. Additionally, the cushion water bypass drain valve on Malo #8 was not functioning. This valve is designed to prevent water from entering the retort during a thermal process. It was also noted that the overflow drain valve on Malo #8 would randomly become caught in an open position during the cook phase of operation.

SEE REVERSE OF THIS PAGE	RTN JTB, CDB, EHH/GH	DATE ISSUED 08/10/2007

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202	07/17/2007 - 08/10/2007* FEI NUMBER 1010894

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OBSERVATION 4

The condensate bleeder was not checked with sufficient frequency to ensure removal of condensate or equipped with an automatic alarm system for the continuous monitoring of condensate bleeder functioning.

Specifically, the high condensate alarm on Malo #8 was observed to be intermittently non-functioning. On 7/19/07, a stream of water was observed flowing from the condensate bleeder for approximately 5 minutes and the condensate alarm never turned on. In addition, the retort operators stated the high condensate alarm on Malo #8 was often perceived as a false alarm. The reason cited was a mineral build-up on the sensor from hard water used in processing.

OBSERVATION 5

Required information was not entered on designated forms at the time the observation was made by the retort or processing system operator or designated person.

Specifically, on 7/18/07 it was observed that a retort operator had completed a thermal process cycle on Malo #8 and failed to record the second mercury-in glass and temperature recorder reading. This same Malo #8 cycle showed the retort operator failed to record 4 of the 6 required condensate bleeder checks.

OBSERVATION 6

Failure to maintain fixtures in repair sufficient to prevent food from becoming adulterated.

Specifically, routine maintenance is needed on the Malo 1-10 line. This was evidenced by a control panel light bulb burned out on Malo #5, valves on Malo's #8 and #5 not working, and the high water fill sensor in the cushion water tank for these Malo's not functioning properly. Also, it was observed that the steam spreaders in the bottom of vertical still retorts #1 and #2 in the kosher room were broken and the spreader in the front vertical #65 was broken.

OBSERVATION 7

Failure to properly adjust the temperature-recording device. The temperature recorded on the temperature-recording device chart was higher than the mercury-in-glass thermometer during processing.

Specifically, this was observed on 1/3/07, Malo #5, chart reading 271 and MIG reading 254; 1/12/07, Malo #5, chart again reading 10 degrees higher than the MIG; 1/19/07, Malo #6, chart at 251 and MIG reading 248; 6/4/07, Malo #6, chart recorder at 246 and MIG at 236; 6/18/07, Malo #7 & #3, the chart recorder was 3 degrees higher than the MIG; and lastly, 6/29/07, Malo #7, recording chart reading 250 and MIG at 247.

SEE REVERSE OF THIS PAGE		DATE ISSUED
		08/10/2007

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Augusta, GA 30901-3929	Low Acid Canned Food Manufacturer

*** DATES OF INSPECTION:**
07/17/2007(Tue), 07/18/2007(Wed), 07/19/2007(Thu), 07/20/2007(Fri), 07/21/2007(Sat), 07/22/2007(Sun), 07/24/2007(Tue), 07/25/2007(Wed), 07/26/2007(Thu), 07/27/2007(Fri), 07/30/2007(Mon), 07/31/2007(Tue), 08/01/2007(Wed), 08/02/2007(Thu), 08/03/2007(Fri), 08/06/2007(Mon), 08/07/2007(Tue), 08/08/2007(Wed), 08/09/2007(Thu), 08/10/2007(Fri)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Robert P. Neligan, Investigator, Investigator

Claudette D. Brooks, Investigator

James P. Lewis, Investigator

Theresa L. Stewart, Investigator

Ernest H. Blackwood, Investigator

Michael S. Mignogna, Investigator

SEE REVERSE OF THIS PAGE	DATE ISSUED
	08/10/2007

Botulism Associated with Canned Chili Sauce, July-August 2007

Questions and Answers Related to the Outbreak of Botulism Associated with Canned Chili Sauce

Information updated as of August 24, 2007

Advice to Consumers

Public health officials in Indiana, Texas, Ohio, and at CDC are investigating an outbreak of botulism associated with canned hot dog chili sauce manufactured by Castleberry's Food Company. Foodborne botulism is a rare but serious paralytic illness caused by consuming foods that contain botulinum toxin, a nerve toxin that is produced by the bacterium *Clostridium botulinum*.

Due to possible contamination with botulinum toxin, CDC, the Food and Drug Administration (FDA), and the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS) are advising persons not to eat certain canned food products manufactured by Castleberry's Food Company. These include certain Castleberry's brands as well as products distributed under other brand names. The recall includes some canned dog food. A listing of the recalled products can be found at the following websites:

- **http://www.castleberrys.com/news_productrecall.asp** (for all products)
- **http://www.fda.gov/opacom/7alerts.html** (for FDA-regulated products)
- **http://www.fsis.usda.gov/Fsis_Recalls/index.asp** (for UDSA-regulated products)

Other foods that should be discarded are those recalled products with missing or unreadable "best by" dates; foods that may have been prepared with a recalled product; and canned chili sauce, chili, beef stew, hash, corned beef hash, barbecue pork, barbecue beef, chip beef, Brunswick stew, sausage gravy or canned dog food if the brand is not known.

As of August 24, 2007, eight cases of botulism have been reported to CDC from Indiana (2 cases), Texas (3 cases), and Ohio (3 cases). The illness onset dates range from June 29 to August 7, 2007. All eight persons were reported to have consumed hot dog chili sauce made by Castleberry's Food Company. The two cases in Indiana occurred in two persons who shared a meal that included Castleberry's hot dog chili sauce the day before illness onset. Botulinum toxin was identified in both patients' sera and leftovers containing hot dog chili sauce collected from the patients' refrigerator. The three cases in Texas occurred in two siblings and their mother, who shared a meal containing Castleberry's hot dog chili sauce the day before the siblings became ill. The three Ohio cases occurred in unrelated persons who consumed Castleberry's hot dog chili sauce in the week before

illness onset. One person reported consuming the chili sauce in early August, after the product was recalled. Botulinum toxin was identified in leftover chili sauce collected from this patient's refrigerator.

CDC OutbreakNet (the network of epidemiologists and other public health officials who investigate outbreaks of foodborne, waterborne, and other enteric illnesses nationwide) staff shared the initial investigation findings with colleagues at the FDA. After being informed about the outbreak by the FDA, the company that manufactures the Castleberry's brand hot dog chili sauce and other products issued a **voluntary recall** on July 18, 2007. The recall was expanded on July 21.

Persons with signs or symptoms of botulism who have eaten hot dog chili sauce or any of the other recalled products manufactured by Castleberry's Food Company are advised to immediately contact their health care provider. These include new onset of double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, or muscle weakness. If untreated, the illness may progress from head to toe, with paralysis of the face, arms, breathing muscles, trunk, and legs. Symptoms generally begin 18 to 36 hours after eating a contaminated food, but they can occur as early as 6 hours or as late as 10 days. Health care providers evaluating persons with signs of botulism should contact their State health department immediately. CDC provides 24/7 consultation on botulism to State health departments and releases antitoxin for treatment.

Advice to Consumers

- **Castleberry's Product Recall Information**
- **July 30: MMWR Dispatch**
- **July 21: FDA Consumer Warning**
- **July 18: FDA Consumer Warning**
- **FSIS Recall: Product Labels**
- **Questions and Answers Related to this Outbreak**
- **More information about *Clostridium botulinum***

* Links to non-Federal organizations found at this site are provided solely as a service to our users. These links do not constitute an endorsement of these organizations or their programs by CDC or the Federal Government, and none should be inferred. CDC is not responsible for the content of the individual organization Web pages found at these links.

Page last modified: August 24, 2007
Content Source: **National Center for Zoonotic, Vector-Borne, and Enteric Diseases (ZVED)**

Page Located on the Web at http://www.cdc.gov/botulism/botulism.htm

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Dole Fresh Vegetables Announces Voluntary Recall of 'Dole Hearts Delight' Packaged Salads

Contact:
Marty Ordman
1-818-874-4834

FOR IMMEDIATE RELEASE --Monterey, Calif. -- Sept. 17, 2007 — Dole Fresh Vegetables, a division of Dole Food Company, Inc., today announced that it is voluntarily recalling all salad bearing the label "Dole Hearts Delight" sold in the U.S. and Canada with a "best if used by (BIUB)" date of September 19, 2007, and a production code of "A24924A" or "A24924B" stamped on the package. The "best if use by (BIUB)" code date can be located in the upper right hand corner of the front of the bag. The salad was sold in plastic bags of 227 grams in Canada and one-half pound in the U.S., with UPC code 071430-01038.

Symptoms of E. coli O157:H7 exposure could include stomach cramps and diarrhea. Bloody diarrhea may develop. E. coli disease sometimes leads to a complication called hemolytic uremic syndrome (HUS). If you exhibited any of these symptoms within 3 to 5 days of consuming any of the products specified above, seek medical attention.

To date, Dole has received no reports that anyone has become sick from eating these products. The recall is occurring because a sample in a grocery store in Canada was found through random screening to contain E. coli O157:H7. No other Dole salad products are involved.

Eric Schwartz, President, Dole Fresh Vegetables, stated: "Our overriding concern is for consumer safety. We are working closely with the U.S. Food and Drug Administration, the Canadian Food Inspection Agency, and several U.S. state health departments."

Consumers who may still have any of the "Dole Hearts Delight" salads with a "best if used by date" of September 19 and a production code of "A24924A" or "A24924B" should dispose of the product. This product was sold in Ontario, Quebec and the Maritime Provinces in Canada and in Illinois, Indiana, Maine, Michigan, Mississippi, New York, Ohio, Pennsylvania, Tennessee and neighboring states in the U.S. Consumers can call the Dole Consumer Center toll-free at 800-356-3111. Consumers are reminded that products should not be consumed after the "best if used by" date.

#

Photo: Dole Hearts Delight

FDA's Pilot Program to Better Educate Consumers about Recalled Food Products

RSS Feed for FDA Recalls Information [what's this?]

Get free e-mail alerts about Class I recalls

SFGate.com

DAILY DIGEST

George Raine, Verne Kopytoff
Tuesday, September 18, 2007

E. coli scare prompts recall of bagged lettuce by dole

Dole Food Co. recalled bags of lettuce labeled Dole Hearts Delight on Monday after routine testing found E. coli bacteria in a sample from a grocery store in Canada.

There have been no reports of illness, said Marty Ordman, a spokesman for Dole, based in Westlake Village (Los Angeles County).

The product is not sold in California but is available in Ontario, Quebec and the maritime provinces of Canada, as well as in at least nine Midwest and East Coast states. The recalled packages are marked with a "best if used by" date of Sept. 19 and a production code of A24924A or A24924B stamped on the package.

Ordman said Dole Hearts Delight is a mix of romaine, green leaf and butter lettuce that was grown in the Salinas Valley in California as well as in Colorado and Ohio. It was processed at a Dole plant in Springfield, Ohio, on Sept. 6. Some 528 bags of lettuce were distributed in Canada and another 4,500 bags in the United States, Ordman said.

A recall of spinach produced by Metz Fresh LLC of King City (Monterey County) was announced Aug. 30 when a sample tested positive for salmonella bacteria.

Last year, Dole spinach - sold in a co-packaging agreement with Natural Selection Foods of San Juan Bautista (San Benito County) - was the source of an E. coli bacteria outbreak that killed three people and sickened 205 around the country.

That outbreak led to an effort by state Sen. Dean Florez, D-Shafter (Kern County), to regulate the leafy green industry. The legislation was shelved this year by the Assembly Agriculture Committee when members said they preferred a voluntary program by growers to adhere to safety standards developed by the industry.

- George Raine

Yahoo asks a select few to do the mash

Invitations to a small group of users went out Friday to participate in Yahoo's latest effort in social networking, Mash (*blog.mash.yahoo.com*).

The Web site is similar to rivals Facebook and MySpace, with modules titled Friends, About Me

and My Stuff (for photos and videos). Users can also add from a list that includes Asteroids (the video game), YouTube and Kaleidoscope.

There's no word yet on when Mash will open to the rest of the world or what will happen to Yahoo 360, a social-networking service that never caught on.

- Verne Kopytoff

http://sfgate.com/cgi-bin/article.cgi?f=/c/a/2007/09/18/BU7SS80DQ.DTL

This article appeared on page **C - 2** of the San Francisco Chronicle

washingtonpost.com

Inspectors Verify Abuse Of Cows in California

Mistreatment Was Captured on Video At Slaughterhouse

By Rick Weiss
Washington Post Staff Writer
Thursday, February 7, 2008; A02

Employees at the now-closed Southern California slaughterhouse where inhumane treatment of cows was captured on a gruesome undercover video committed "egregious violations" of federal animal care regulations, the U.S. Agriculture Department has determined.

The agency's Food Safety and Inspection Service formally withdrew its inspectors from Hallmark Meat Packing in Chino on Monday after verifying the mistreatment and discovering other problems at the plant, an agency official said yesterday.

"They've got some obvious multilevel issues," said Kenneth Petersen, assistant administrator of field operations, which inspects the nation's 6,200 meat processing plants. "For them to get out from under this, they are going to have to explain what exactly happened, why it happened and what are the multiple measures they're going to put in place to prevent it from happening again."

The problems came to light last week when the Humane Society of the United States released video footage taken by a Hallmark employee who was working undercover for the Washington-based animal welfare group. The film showed workers using chains to drag cows unable to stand; shoving and rolling crippled cows with forklifts; and rampant use of electric prods to drive infirm animals to slaughter.

Under state and federal regulations and laws, livestock must be treated humanely, and only animals that can walk under their own power can be slaughtered -- a way of minimizing the chances that diseased animals will enter the food supply.

Westland Meat, a partner of Hallmark, has been a major supplier of beef for the nation's school lunch program and other federal food programs. The Agriculture Department's Agricultural Marketing Service (AMS), which had contracted with Westland for the school lunch program, suspended that relationship Jan. 30 when the video was released. That effectively shuttered Hallmark, Petersen said, since AMS was the company's major client.

School systems and other outlets across the country scrambled to pull the company's products.

On Monday, after several days at the plant, federal investigators concluded that the video was authentic. They also found that the company did not have adequate policies to assure humane treatment and that some policies it did have -- such as one requiring that livestock unable to stand be rejected -- were ignored. Petersen said at least one worker or official at the plant "made some admission of guilt."

Petersen said the department's Office of the Inspector General is also investigating. It can subpoena evidence and refer findings to the Justice Department for criminal prosecution.

Lawrence Miller, director of business affairs at Hallmark, said only two employees violated rules and both have been fired. No supervisor or manager was aware of the mistreatment, he said.

Miller said the company is preparing to implement "drastic measures" to prevent any future violations, including psychological screening of employees and continuous video camera surveillance. Miller insisted, as has company head Steve Mendell, that Hallmark has never been found in violation of USDA rules since the current management team took over in 1998.

But USDA records indicate the company was cited in 2005 for several animal welfare violations, including "too much electric prodding."

Asked how that comported with his claim of no citations, Miller said he was unaware of it.

"We certainly wouldn't have failed to disclose that if we knew it was in the public record," he said. "You know more than we do."

Julie Janovsky of Farm Sanctuary, a Watkins Glen, N.Y.-based group that filmed the use of forklifts on livestock at Hallmark in 1993, called for better federal oversight: "It is obvious that the USDA needs to significantly increase its enforcement of laws to protect downed animals across the country."

Petersen would not predict how long it might be before the plant was brought into compliance.

"It's in their court," he said. "If they respond tomorrow, that's fine with me. If they respond in a month, that's fine with me."

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Inland News

Criminal investigators look at slaughterhouse

CHINO ABUSE CASE: The USDA's inspector general will search for evidence of wrongdoing.

Download story podcast

10:00 PM PST on Friday, February 8, 2008

By JANET ZIMMERMAN
The Press-Enterprise

The criminal investigative arm of the U.S. Department of Agriculture is looking into allegations of inhumane practices at the Chino slaughterhouse where employees were secretly videotaped pushing cattle with forklifts and shooting water up their noses, federal officials said Friday.

The USDA also announced a 10-day extension, until Feb. 19, on the hold of ground beef from Hallmark Meat Packing and its distributor, Westland Meat Co., to schools and programs that serve the elderly and needy nationwide, officials said in a conference call with reporters.

Schools in all 50 states and Washington, D.C., were ordered to suspend use of meat from the company. The USDA will determine whether the meat can be used or must be destroyed.

The issue is whether the company processed "downer" cows -- those too sick or injured to stand or walk on their own. The USDA prohibits downed cows from entering the food supply because of the increased risk that the animals could be infected with mad cow disease.

An undercover investigator from the Humane Society of the United States, who shot video of the abuses while working at Hallmark late last year, said he saw such cows enter the slaughterhouse. His video shows workers poking downed cows in the eyes, stinging them with electrical prods and using the prongs of forklifts, allegedly to get them upright enough to pass federal inspection so they could be killed and sold as food.

USDA food safety officials said there is no evidence that downer cattle at Hallmark entered the food supply. The facility processed about 500 retired dairy cows per day until operations were suspended last week.

USDA Investigating

The Hallmark probe is now in the hands of the USDA's Office of the Inspector General, which investigates fraud and abuse in Department of Agriculture programs and operations and in non-government entities that receive USDA assistance.

If evidence of wrongdoing is found, the case would be turned over to the U.S. Attorney's Office and Department of Justice, said Kenneth Petersen, an assistant administrator with the Agriculture Department's Food Safety and Inspection Service.

The role of USDA inspectors at Hallmark also could be examined, specifically how the abuse occurred despite daily inspections, Petersen said.

"How it went undetected is certainly going to be part of the investigation," he said. "When did it occur? Did they have knowledge of when my inspectors would be around? ... How, if this was occurring on an ongoing basis, they (inspectors) were not aware of it."

The inspector general's investigation is separate from the USDA's suspension of operations at the plant this week, Petersen said. Although Hallmark's management voluntarily shut down last week after the abuse story broke, the federal agency's action means the plant can't reopen until the USDA gives the go-ahead.

Hallmark/Westland management said two employees pictured on the videotape were immediately fired. But that alone won't be enough to resume operations at the plant, Petersen said.

The company would have to implement more employee training, ongoing supervision and better surveillance of what goes on in the pens, he said.

"The plant needs to decide if and when they want to respond," Petersen said. "It's their timeline."

Previous Problems

Hallmark was cited in 2005 after an inspector observed overuse of electrical prods and other problems, including exposed nails and gaps in the concrete that could hurt animals. The company took quick corrective action, Petersen said.

The overuse of prods raised issues of the facility's layout and design and the employees' training, he said.

The problems were considered "non-egregious," and the plant has gone two years without further issues, he said. "We would consider that a substantial period of compliance."

An audit in May by the same inspector found Hallmark in compliance, Petersen said.

"The facility concerns we had had been significantly corrected," he said.

The company also received a USDA administrative action in 2002 for having a plan that didn't adequately address new government requirements for controlling E. coli, USDA spokeswoman Amanda Eamich said Friday. E. coli is a bacterium that can cause severe diarrhea.

While it wasn't common, other slaughterhouses also required "extra guidance" on the new regulations, she said, though she couldn't elaborate on what the deficiencies were.

A New York-based animal rights group, Farm Sanctuary, contends the problem of downer cows is common. Spokeswoman Tricia Berry said group members in 1993 filmed livestock at Hallmark being lifted with forklifts to get them on their feet, and prompted introduction of a "downer" cow law in California the next year.

Farm Sanctuary, through its own investigations and USDA records, has documented numerous downer cow violations nationwide in the years since, Berry said.

"This is incredibly widespread," she said.

Reach Janet Zimmerman at 951-368-9586 or jzimmerman@pe.com

USDA Food Safety and Inspection Service

Recall Release

CLASS II RECALL
HEALTH RISK: LOW

Congressional and Public Affairs
Amanda Eamich (202) 720-9113
FSIS-RC-005-2008

CALIFORNIA FIRM RECALLS BEEF PRODUCTS DERIVED FROM NON-AMBULATORY CATTLE WITHOUT THE BENEFIT OF PROPER INSPECTION

WASHINGTON, Feb. 17, 2008 – Hallmark/Westland Meat Packing Co., a Chino, Calif., establishment, is voluntarily recalling approximately 143,383,823 pounds of raw and frozen beef products that FSIS has determined to be unfit for human food because the cattle did not receive complete and proper inspection. Through evidence obtained by FSIS, the establishment did not consistently contact the FSIS public health veterinarian in situations in which cattle became non-ambulatory after passing ante-mortem inspection, which is not compliant with FSIS regulations.

Such circumstances require that an FSIS public health veterinarian reassess the non-ambulatory cattle which are either condemned and prohibited from the food supply, or tagged as suspect. Suspect cattle receive a more thorough inspection after slaughter than is customary.

This noncompliant activity occurred occasionally over the past two years and therefore all beef product produced during the period of time for which evidence indicates such activity occurred has been determined by FSIS to be unfit for human consumption, and is, therefore, adulterated.

This recall is designated as Class II due to the remote probability that the beef being recalled would cause adverse health effects if consumed. FSIS made this determination because the animals passed ante-mortem inspection but should have been identified as suspect requiring additional inspection after slaughter to determine if there is evidence of disease, injury, or other signs of abnormalities that may have occurred after ante-mortem inspection.

In July 2007, FSIS issued a final rule "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle." This rule requires that a case by case disposition must be made by an FSIS Public Health Veterinarian for every animal that becomes non-ambulatory disabled ("downer") after passing ante-mortem inspection.

The prohibition of downer cattle from entering the food supply is only one measure in an interlocking system of controls the federal government has in place to protect the food supply. The government has multiple safeguards regarding BSE in place and the prevalence of the disease in the United States is extremely low. Other BSE security measures include the feed ban that prohibits feeding ruminant protein to other ruminants and an ongoing BSE surveillance program that began before the confirmation of the first BSE positive cow in the U.S. in 2003.

As another measure to reduce the risk of potential exposure to consumers, FSIS requires the removal of specified risk materials (SRM) so they do not enter the food supply. Several FSIS line inspectors are stationed at designated points along the production line where they are able to directly observe SRM removal activities.

The products subject to this recall were sent to wholesale distributors nationwide in bulk packages and are not available for direct purchase by consumers. All products subject to recall bear the establishment number "EST. 336" inside the USDA mark of inspection. The products were produced on various dates from Feb. 1, 2006 to Feb. 2, 2008. Companies are urged to check their inventories and hold the products until the recalling firm makes arrangements for final disposition of the products.

The following products are subject to recall: [View Labels]

- Various weight boxes of "WESTLAND MEAT CO., BURRITO FILLING MIX."
- Various weight boxes of "WESTLAND MEAT CO., PACKED FOR JACOBELLIES SAUSAGE CO., 74/26 GROUND BEEF."
- Various weight boxes of "WESTLAND MEAT CO., RAW GROUND BEEF MEATBALL MIX FOR FURTHER PROCESSING."
- Various weight boxes of "WESTLAND MEAT CO., COARSE GROUND BEEF 'FOR COOKING ONLY', FAT: 15%."
- Various weight boxes of "WESTLAND MEAT CO., COARSE GROUND BEEF 'FOR COOKING ONLY'."
- Various weight boxes of "WESTLAND MEAT CO., COARSE GROUND BEEF TO BE FURTHER PROCESSED INTO COOKED ITEMS, FAT: 15%."
- Various weight boxes of "WESTLAND MEAT CO., COARSE GROUND BEEF 85/15."
- Various weight boxes of "WESTLAND MEAT CO., COARSE GROUND BEEF 93/7."
- Various weight boxes of "WESTLAND MEAT CO., FINE GROUND BEEF 'FOR COOKING ONLY', FAT: 15%."
- Various weight boxes of "WESTLAND MEAT CO., FINE GROUND BEEF 'FOR COOKING ONLY'."
- Various weight boxes of "WESTLAND MEAT CO., 90 - 10% GROUND BEEF, 3/16 GRIND."
- Various weight boxes of "WESTLAND MEAT CO., GROUND BEEF 1 LB. PACKAGE, FAT: 15%."
- Various weight boxes of "WESTLAND MEAT CO., GROUND BEEF, FAT: 15%."
- Various weight boxes of "WESTLAND MEAT CO., RAW BONELESS BEEF TRIMMINGS, 'FOR COOKING ONLY'."
- Various weight boxes of "WESTLAND MEAT CO., RAW BONELESS BEEF, 'FOR COOKING ONLY'."
- Various weight boxes of "WESTLAND MEAT CO., BEEF GROUND 50/50% LEAN."
- Various weight boxes of "WESTLAND MEAT CO., BEEF GROUND 73/27% LEAN."
- Various weight boxes of "WESTLAND MEAT CO., BEEF GROUND 81/19% LEAN."
- Various weight boxes of "WESTLAND MEAT CO., BONELESS BEEF 90/10."
- Various weight boxes of "WESTLAND MEAT CO., GROUND PORK FOR FURTHER PROCESSING NOT TO EXCEED 30% FAT."
- Various weight boxes of "PACKED FOR: KING MEAT CO., BEEF TRI TIP."
- Various weight boxes of "PACKED FOR: KING MEAT CO., BEEF TOP SIRLOIN BUTT."
- Various weight boxes of "PACKED FOR: KING MEAT CO., BEEF STRIP SIRLOIN."
- Various weight boxes of "PACKED FOR: KING MEAT CO., BEEF RIB EYE LIP-ON."
- Various weight boxes of "PACKED FOR: KING MEAT CO., BEEF PISMO TENDERLOIN."
- Various weight boxes of "PACKED FOR: KING MEAT CO., BEEF O/S SKIRT."
- Various weight boxes of "PACKED FOR: KING MEAT CO., BEEF I/S SKIRT."
- Various weight boxes of "PACKED FOR: KING MEAT CO., BEEF FLANK STEAK."
- Various weight boxes of "PACKED FOR: KING MEAT CO., BEEF BOTTOM SIRLOIN FLAP."
- Various weight boxes of "PACKED FOR: KING MEAT CO., BEEF STRIP LOIN BONE-IN, FURTHER PROCESS 1X1."

- Various weight boxes of "PACKED FOR: KING MEAT CO., BEEF EXPORT RIB 2X2, FURTHER PROCESS."
- Various weight boxes of *REGAL* brand "USDA SELECT, BEEF RIBEYE ROLL LIP-ON."
- Various weight boxes of *REGAL* brand "USDA CHOICE OR HIGHER, BEEF RIBEYE ROLL LIP-ON."
- Various weight boxes of *REGAL* brand "USDA SELECT, BEEF PLATE, OUTSIDE SKIRT."
- Various weight boxes of *REGAL* brand "USDA CHOICE OR HIGHER, BEEF PLATE, OUTSIDE SKIRT."
- Various weight boxes of *REGAL* brand "USDA SELECT, BEEF PLATE, INSIDE SKIRT."
- Various weight boxes of *REGAL* brand "USDA CHOICE OR HIGHER, BEEF PLATE, INSIDE SKIRT."
- Various weight boxes of *REGAL* brand "USDA SELECT, BEEF LOIN, STRIP LOIN, BONELESS."
- Various weight boxes of *REGAL* brand "USDA CHOICE OR HIGHER, BEEF LOIN, STRIP LOIN, BONELESS."
- Various weight boxes of *REGAL* brand "USDA SELECT, BEEF LOIN, BOTTOM SIRLOIN BUTT, FLAP, BONELESS."
- Various weight boxes of *REGAL* brand "USDA CHOICE OR HIGHER, BEEF LOIN, BOTTOM SIRLOIN BUTT, FLAP, BONELESS."
- Various weight boxes of *REGAL* brand "USDA SELECT, BEEF LOIN, TOP SIRLOIN BUTT, BONELESS."
- Various weight boxes of *REGAL* brand "USDA CHOICE OR HIGHER, BEEF LOIN, TOP SIRLOIN BUTT, BONELESS."
- Various weight boxes of *REGAL* brand "USDA SELECT, BEEF LOIN, TENDERLOIN, FULL, SIDE MUSCLE ON, DEFATTED."
- Various weight boxes of *REGAL* brand "USDA CHOICE OR HIGHER, BEEF LOIN, TENDERLOIN, FULL, SIDE MUSCLE ON, DEFATTED."
- Various weight boxes of *REGAL* brand "USDA SELECT, BEEF FLANK STEAK."
- Various weight boxes of *REGAL* brand "USDA CHOICE OR HIGHER, BEEF FLANK STEAK."
- Various weight boxes of *REGAL* brand "USDA SELECT, BEEF, BOTTOM SIRLOIN BUTT TRI TIP BONELESS."
- Various weight boxes of *REGAL* brand "USDA CHOICE OR HIGHER, BEEF, BOTTOM SIRLOIN BUTT TRI TIP BONELESS."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF LIVERS."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF FEET."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF TRIPE."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF REGULAR TRIPE."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF HONEYCOMB TRIPE."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF TAILS."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF CHEEK MEAT."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF TONGUES."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF TONGUE TRIMMINGS."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF BONELESS."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF RIBS."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF HEARTS."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF CHEEKS."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF PLATES."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF SMALL INTESTINES."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF LIPS."
- Various weight boxes of "HALLMARK MEAT PACKING BEEF SPLEENS."

- Various weight boxes of "HALLMARK MEAT PACKING BEEF SALIVARY GLANDS, LYMPH NODES AND FAT [TONGUES]."
- Six-gallon containers of "HALLMARK MEAT PACKING BEEF BILE."
- One- and six-gallon containers of "HALLMARK MEAT PACKING BEEF BLOOD, .2% SODIUM CITRATE ADDED."

Some of the Westland Meat Co. branded products were purchased for Federal food and nutrition programs and, since Jan. 30, 2008, USDA has had an administrative hold on all products from Westland Meat Co. in all of these outlets including, in the National School Lunch Program, the Emergency Food Assistance Program and the Food Assistance Program on Indian Reservations. Based on this Class II recall, officials of the Food and Nutrition Service and Agricultural Marketing Service will work closely with State food and nutrition officials to minimize any disruptions caused by the removal and disposal of recalled Westland Meat Co. products.

Media and consumers with questions about the recall should contact company Plant Manager Stan Mendell or Food Safety Consultant Steve Sayer at (909) 590-3340.

Consumers with food safety questions can "Ask Karen," the FSIS virtual representative available 24 hours a day at AskKaren.gov. The toll-free USDA Meat and Poultry Hotline 1-888-MPHotline (1-888-674-6854) is available in English and Spanish and can be reached from l0 a.m. to 4 p.m. (Eastern Time) Monday through Friday. Recorded food safety messages are available 24 hours a day.

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NOTE: Access news releases and other information at the FSIS Web site at http://www.fsis.usda.gov

USDA RECALL CLASSIFICATIONS

Class I This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

Class II This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.

Class III This is a situation where the use of the product will not cause adverse health consequences.

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February 22, 2008

Beef Industry Presses For Reduced Recall

By DAVID KESMODEL and ELIZABETH WILLIAMSON
February 22, 2008; Page A2

U.S. Department of Agriculture officials said yesterday they are still tracing 15 million of the 143 million pounds of beef involved in the nation's largest-ever meat recall, but the meat industry appears to be pressing the agency to scale back the recall.

Just days after the recall was announced, industry representatives were talking with federal food-safety regulators about narrowing its scope, according to a legal memo reviewed by The Wall Street Journal.

The USDA has said much of the recalled beef, which was produced by Hallmark/Westland Meat Packing Co., of Chino, Calif., probably has been consumed. No illnesses from the meat have been reported.

In two conference calls this week, industry and USDA officials discussed the possibility of excluding from the recall Hallmark/Westland beef that was mixed with other suppliers' meat and sent to retail and wholesale customers, according to a memo written by an employee of Olsson Frank Weeda Terman Bode Matz PC. The Washington law firm represents several food companies. The department appears to have since decided against narrowing the scope.

It wasn't clear how much meat such an exemption might involve. The recall, announced Sunday, came about three weeks after the Humane Society of the United States released an undercover video showing workers at Hallmark/Westland's Chino plant forcing sick or injured cows into slaughter by kicking them or ramming them with forklifts. Cows that can't walk or stand on their own are generally banned from the food supply.

Such "downer" cows can be sources of mad-cow disease, which can cause a rare but fatal brain disorder in humans.

Though USDA and the industry discussed excluding some meat shipped to retailers and wholesalers from the recall, any Hallmark/Westland meat supplied to the federal school-lunch program -- whether mingled with other suppliers' meat or not -- would have to be recalled. On one call this week with about 20 processors, agency officials reaffirmed all meat containing Hallmark/Westland products furnished to schools must be destroyed. But on a separate call, the USDA said it would take a "different approach" for Hallmark/Westland meat that was mixed with other suppliers' meat and already sent to retail or wholesale customers, the law-firm memo said. "If a processor or grinder has records demonstrating that products were produced using less than 100% of recalled Westland meat for the meat component, then there is no need...to retrieve that 'commingled' product," the memo said.

Officials of USDA's Food Safety and Inspection Service indicated that this approach wasn't "a 'road map' for future" recalls, but was due to the low potential for health risks from the Hallmark/Westland meat, the

memo said. The document added that if a processor or meat grinder produced "any" products that have some fraction of recalled Westland meat, and the product is under its direct control, the product should be destroyed.

A USDA spokeswoman declined to comment on the memo. "The recall is as it was issued on Sunday....We are following the directives, as we do for any recall," said Amanda Eamich of the Food Safety and Inspection Service. Steve Mendell, Hallmark/Westland's president, didn't return a phone call seeking comment.

Rob McLaughlin, vice president at Advance Food Co., a food-service company in Enid, Okla., that supplies school systems, said it was unfortunate the USDA appears to have been uncertain how to handle the issue of commingled meat. Advance received beef from Hallmark/Westland through the national school-lunch program.

Mr. McLaughlin said his company feels "sick" that millions of pounds of food will be wasted when "no one is sick" and the food is covered by a Class II recall, meaning the USDA thinks there is little health risk involved.

Yesterday, during a conference call with reporters, USDA officials said more than one-third of the recalled beef wound up in federal school-lunch programs. That is about 50 million pounds of beef, said Eric Steiner, deputy administrator of the USDA's Food and Nutrition Service. About 20 million pounds have been eaten, 15 million pounds are in storage, and another 15 million pounds are being traced.

"I cannot tell you how many locations the product has gone to," said the USDA's Kenneth Petersen. "Our focus is identifying the locations and making sure the product is under control."

Hallmark/Westland, which has closed pending a USDA investigation, has 250 employees and about 10 USDA inspectors on-hand, said Juan Acevedo, the company's controller.

Write to David Kesmodel at david.kesmodel@wsj.com[1]

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

New Era Canning Company Recalls Canned GFS Fancy Blue Lake Cut Green Beans Because of Possible Health Risk

Contact:
Linda Miller
1-800-282-9007 Ext 111

FOR IMMEDIATE RELEASE --New Era, MI -- December 21, 2007 --- New Era Canning Company of New Era, Michigan is voluntarily recalling 171 cases/ 6 cans per case of 6 lbs. 5 oz. GFS Fancy Blue Lake Cut Green Beans, 4 Sieve, lot code 19H7FL , because they may be contaminated with Clostridium botulinum, a bacterium which can cause life-threatening illness or death from botulism. Consumers are warned not to use the product even if it does not look or smell spoiled.

Botulism, a potentially fatal form of food poisoning, can cause the following symptoms: general weakness, dizziness, double-vision and trouble speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these symptoms should seek immediate medical attention. The incubation period can be 2 hours to 2 weeks; in most cases the symptoms appear after 12 to 24 hours.

The canned green beans were distributed to foodservice customers in Alabama, Arkansas, Georgia, Illinois, Indiana, Kentucky, Mississippi, Missouri, North Carolina, Tennessee, and Virginia and sold through GFS Marketplace stores in Indiana, Kentucky, and Tennessee.

The canned green beans are packaged in 6 lbs. 5 oz. cans under the GFS brand (GFS reorder #118737; UPC 93901 11873) with lot code 19H7FL printed on the end of the can. No other reorder numbers or lots are included in this recall.

No illnesses have been reported to date in connection with this problem.

The potential contamination of the product was found through testing by the Food and Drug Administration. New Era Canning in conjunction with the US Food and Drug Administration and the Michigan Department of Agriculture is thoroughly evaluating all processes and procedures to determine the cause of the problem.

Any food that may be contaminated should be disposed of carefully. Even tiny amounts of toxins ingested, inhaled, or absorbed through the eye or a break in the skin can cause serious illness. Skin contact should be avoided as much as possible, and the hands should be washed immediately after handling the food. Customers should not be encouraged to return product to Gordon Food Service. Customers who have the product or any foods made with these products should throw them away immediately. Double bag the cans in plastic bags that are tightly closed then place in a trash receptacle for non-recyclable trash outside of the home. Restaurants and institutions are encouraged to assure that such products are only placed in locked receptacles which are not accessible to the public. Additional instructions for safe disposal can be found at www.cdc.gov/botulism/botulism_faq.htm.

Anyone with questions can call FDA at 1-888-SAFEFOOD.

Customers with questions may contact New Era Canning at 1-800-282-9007 Ext. 111.

Photo: New Era Canned GFS Fancy Blue Lake Cut Green Beans

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

New Era Canning Company Announces New Recall of Certain Lots of Mexican-style Chili Beans, Green Beans and Dark Red Kidney Beans Because of Possible Health Risk

Contact:
Linda Miller
1-800-282-9007 Ext 111

FOR IMMEDIATE RELEASE – New Era, MI – January 8, 2008 — New Era Canning Company of New Era, Michigan is announcing a new recall to include Mexican style chili beans, green beans, and dark red kidney beans that were shipped to food service and retail customers because a records review identified the possibility that a small number of cans from each lot may not have been adequately cooked.

New Era is recalling these products as a precautionary measure because cans of vegetables that have not been adequately cooked have the potential for the growth of *Clostridium botulinum*, a bacterium which can cause botulism, a potentially fatal form of food poisoning. Botulism can cause the following symptoms: general weakness, dizziness, double-vision and trouble speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these symptoms should seek immediate medical attention. The incubation period can be 2 hours to 2 weeks; in most cases the symptoms appear after 12 to 24 hours.

This recall only affects a small number of cases from the products with the specific codes listed below: **GFS brand Fancy Mexican Style Chili Beans in 6 lb. 12 oz. cans,** GFS Reorder #192015, UPC 9390119201. The recall is limited to 43 cases of product with 6 cans per case of lot number 00249 5AJ6LC with a 4 digit time stamp number ranging from *2113* through *2235* printed on the end of the can after the lot number (For example: 00249 5AJ6LC 2113). ***Only*** product bearing *time stamps* of 2113 through 2235 are included in the recall. The canned Mexican style chili beans were distributed to Gordon Food Service foodservice customers in Arkansas, Illinois, Indiana, Kentucky, Michigan, Missouri, Tennessee, Virginia and Wisconsin and sold through GFS Marketplace stores in Illinois, Indiana, Kentucky and Michigan.

Kitchen brand Blue Lake Mixed Cuts Green Beans in 6 lb. 6 oz. cans. This recall is limited to 57 cases with 6 cans per case with lot number 00249 6FG5GA printed on the end of the can. (All cans of this lot are under recall). The canned green beans were not sold at retail, but were distributed to a Michigan restaurant by North Oakland Commodities.

Great Value brand Dark Red Kidney Beans in 15.5 oz. cans, UPC 7874237085. This recall is limited to 12 cases with 12 cans per case with lot number 00249 CKJ6LD printed on the end of the can. (All cans of this lot are under recall). This lot of canned dark red kidney beans was sold at Wal-Mart Stores in Arizona, Colorado, Idaho, Montana, Nevada, Utah and Wyoming.

We have been alerted that some of our cans may be missing the can codes. Any cans of these products without a code should not be opened or used, and should be disposed of as outlined below.

Neither New Era or the Food and Drug Administration are aware of any illnesses related to these products. New Era Canning in conjunction with the US Food and Drug Administration and the Michigan Department of Agriculture is thoroughly evaluating all processes and procedures to determine the cause of the problem.

Any food that may be contaminated should be disposed of carefully. Even tiny amounts of toxins ingested, inhaled, or absorbed through the eye or a break in the skin can cause serious illness. Skin contact should be avoided as much as possible, and the hands should be washed immediately after handling the food. Customers who have the product or any foods made with these products should throw them away immediately. Double bag the cans in plastic bags that are tightly closed, then place in a trash receptacle for non-recyclable trash outside of the home. Restaurants and institutions are encouraged to assure that such products are only placed in locked receptacles which are not accessible to the public. Additional instructions

for safe disposal can be found at www.cdc.gov/botulism/botulism_faq.htm. Anyone with questions can call FDA at 1-888-SAFEFOOD.

Customers with questions may contact New Era Canning at 1-800-282-9007 Ext. 111.

Photos: Product Labels

RSS Feed for FDA Recalls Information (what's this?)

Sign up for Recall email updates.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

New Era Canning Company Announces New Nationwide Recall of Green Beans and Garbanzo Beans in #10 cans (6 to 7 pound cans)

Contact:
Linda Miller
1-800-282-9007 Ext 111

FOR IMMEDIATE RELEASE – New Era, MI – January 18, 2008 –– New Era Canning Company of New Era, Michigan is recalling all cans of green beans and garbanzo beans in #10 cans (large cans containing between 6 and 7 pounds) because they may have been processed under conditions which could have led to contamination by *Clostridium botulinum* bacterium spores, which can cause life-threatening illness or death. The codes on the affected product begin with the numbers "00249," or the letters "GREEN" or "GARB". This recall does not include Italian Green Beans because that is a different product.

Clostridium botulinum bacterium spores have the potential for growth that produces a toxin that causes a potentially fatal form of food poisoning - botulism. Symptoms of botulism poisoning in humans can begin from 6 hours to 2 weeks after eating food that contains the toxin. Symptoms may include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, and muscle weakness that moves progressively down the body, affecting the shoulders first, then descending to the upper arms, lower arms, thighs, and calves. Botulism poisoning also can cause paralysis of the breathing muscles, which can result in death unless assistance with breathing (mechanical ventilation) is provided. Individuals who have these symptoms and who may have recently eaten the green beans or garbanzo beans currently under recall or other food products made with these items should seek immediate medical attention.

The issues were uncovered in a FDA inspection of products that were in the company's possession. NO product has tested positive for the toxin and there have been NO cases of botulism reported from these products.

This recall only affects the products in the large #10 cans, the majority of which were potentially sold nationwide to various food service customers. However these products may also have been purchased by consumers at retail stores. The code on the cans may be embossed (stamped into the metal of the can) or printed in ink on one of the metal can ends.

Examples of how a code may appear on a can of green beans are: "00249 2BH7FL", "00249 1515 2BH7FL", "GREEN 2BH7FL" or "GREEN 1515 2BH7FL". (These are not necessarily actual can codes).

Examples of how a code may appear on a can of garbanzo beans are: "00249 34F7LG", "00249 1515 34F7LG", "GARB 34F7LG" or "GARB 1515 34F7LG". (These are not necessarily actual can codes).
New Era Canning, in conjunction with the US Food and Drug Administration and the Michigan Department of Agriculture, is thoroughly evaluating all processes and procedures to determine the cause of the problem.

Any food that may be contaminated should be disposed of carefully. Even tiny amounts of toxins ingested, inhaled, or absorbed through the eye or a break in the skin can cause serious illness. Skin contact should be avoided as much as possible, and the hands should be washed immediately after handling the food. Customers who have the product or any foods made with these products should throw them away immediately. Double bag the cans in plastic bags that are tightly closed, then place in a trash receptacle for non-recyclable trash outside of the home. Restaurants and institutions are encouraged to assure that such products are only placed in locked receptacles which are not accessible to the public. Additional instructions for safe disposal can be found at www.cdc.gov/botulism/botulism_faq.htm. Anyone with questions can call FDA at 1-888-SAFEFOOD.

Customers with questions may contact New Era Canning at 1-800-282-9007 Ext. 111.

The following product labels are affected:

Bunny brand, Distributed by Bunn Capitol Company, Springfield, IL
Blue Lake mixed and shortcut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 6444500193).

Classic Sysco brand, Distributed by Sysco Corporation, Houston, TX.
Blue Lake cut green beans, 3 sieve (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 7486510779).

Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 7486510487).
Garbanzo beans (garbanzo beans, water, salt, calcium chloride, EDTA) in 108.0 oz (6 lb. 12 oz.) cans (UPC 7486510484).

Code brand, Distributed by Code, Atlanta, GA.
Mixed & short cut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 1207310120).
Fancy garbanzo beans without sulfites (garbanzo beans, water, salt, disodium EDTA) in 6 lb. 14 oz. cans (UPC 1207316120).

ComSource brand, Distributed by ComSource, Atlanta, GA.
Blue Lake cut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952333).
Blue Lake cut green beans, 3 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952321).
ComSource Medallion Premium Quality brand, distributed by ComSource, Atlanta, GA.
Fancy Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952325).

ComSource Merit Excellence Food Service brand, Distributed by ComSource, Inc, Atlanta, GA.
Cut Blue Lake green beans, 5 sieve (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952327).
Fancy Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952325).

ComSource Traditional brand, Distributed by ComSource, Atlanta, GA.
Blue Lake cut green beans, mixed and short cut, (green beans, water, salt) in 101 oz (6 lb. 5 oz.) cans (UPC 5254952359).
Cut Blue Lake green beans, 4 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952427).
Cut Blue Lake green beans, 5 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 5254952429).

Frosty Acres Restaurant's Pride Preferred brand, Packed for F.A.B., Inc., Alpharetta, GA.
Fancy Blue Lake cut green beans, 3 sieve (green beans, water, salt), in 101 oz. (6 lb. 5 oz.) cans (UPC 4820067373).
Cut Blue Lake green beans, 4 sieve (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 4820067445).
Blue Lake cut green beans, 5 sieve (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 4820067451).

Fancy cut Blue Lake green beans (green beans, water, salt), in 101 oz. (6 lb. 5 oz.) cans (UPC 4820067339).
Fancy cut Blue Lake green beans, 4 sieve (green beans, water, salt), in 101 oz. (6 lb. 5 oz.) cans (UPC 4820067446).
Mixture of Blue Lake short cut, cut green beans (green beans, water, salt), in 101 oz. (6 lb. 5 oz.) cans (UPC 4820068464).
Fancy garbanzos "chick pea" (garbanzo beans, water, salt, calcium chloride, disodium EDTA) in 111 oz. (6 lb. 15 oz.) cans (UPC 4820068264).

GFS brand, Distributed by Gordon Food Service, Grand Rapids, MI
Fancy Blue Lake cut green beans, 4 sieve (green beans, water, salt) in 6 lb. 5 oz. cans, reorder no. 118737 (UPC 9390111873).
Cut Blue Lake green beans, mixed sieve, (green beans, water, salt) in 6 lb. 5 oz. cans, reorder no. 273856 (UPC 9390127385).

goodtaste brand, Distributed by New Era Canning in New Era, MI.
Cut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 3683512340).

Harvest Value brand, distributed by U.S. Food Service, Columbia, MD
Cut green beans, mixed and short cut, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 173619 (UPC 5810803534).
Cut green beans (green beans, water, salt) in 101 (6 lb. 5 oz.) cans, 170524 (UPC 5810801047).
Cut green beans, short cut (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 173349 (UPC 5810803538).

Kitchen brand, Distributed by Potato Products, Detroit, MI.
5 sieve- EX.-STD. cut Blue Lake green beans (green beans, water, salt) in 6 lb. 6 oz. cans

Kitchen Essentials brand, Distributed by Gordon Food Service, Grand Rapids, MI.
Cut green beans, mixed sieve, (green beans, water, salt) in 6 lb. 6 oz. cans, reorder no. 156337 (UPC 9390115633).

Monarch brand, Distributed by Reid, Murdoch & Co., Columbia, MD

Extra Fancy Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 177039 (UPC 5810811196).
Fancy Blue Lake cut green beans, 3 sieve, (green beans, water, salt) in 101 oz (6 lb 5 oz) cans, 170672 (UPC 5810801040).

Monarch Premium brand, packed for PYA/Monarch, Inc, Greenville, SC.
Fancy Blue Lake cut green beans, 3 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans, 173205 (No UPC code).

Mount Stirling brand, Distributed by Pocahontas Foods USA, Richmond, VA.
Blue Lake cut green beans, 5 sieve, (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 4156033379).

Necco brand, Packed by New Era Canning Company, New Era, MI.
Cut green beans (green beans, water, salt) in 6 lb. 6 oz. cans (UPC 3683513340).

New Era brand, Distributed by New Era Canning Co, New Era, MI.
Veri-Green cut green beans (green beans, water, salt, zinc chloride) in 102 oz. (6 lb. 6 oz.) cans (No UPC code).
Cut green beans (green beans, water, salt) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511340).
Cut Blue Lake green beans, no salt added, (green beans, water) in 102 oz. (6 lb. 6 oz.) cans (No UPC code).
Garbanzo beans (garbanzo beans, water, salt, calcium chloride, EDTA) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511684).

Nugget brand, Distributed by Nugget, Atlanta, GA.
Green beans, 4 sieve, (green beans, water, salt) in 101 oz. (6lb. 5oz.) (UPC 4410540023).
Cut green beans, 5 sieve (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 4410501930).
Veri-green cut green beans (green beans, water, salt, zinc chloride) in 6 lb. 12 oz. cans (UPC 4410502101).
Mixed short cut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 4410518838).
Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 4410501989).

Pocahontas brand, Distributed by Pocahontas Foods USA, Richmond, VA.
Fancy Blue Lake cut green beans, 4 sieve, (Blue Lake green beans, water, salt), 10282, in 6 lb. 5 oz. cans (UPC 4156010282).
Fancy long cut green beans (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 4156010325).
Fancy Blue Lake green beans, 3 sieve, (Blue Lake green beans, water, salt), 10280, in 6 lb. 5 oz. cans (UPC 4156010280).

Reliance Sysco, Distributed by Sysco Corporation, Houston, TX.
Mixed cut green beans (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 7486512175).
Blue Lake cut green beans, 4 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans. (UPC 7486512172).
Blue Lake cut green beans, 5 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 7486512174).

Sysco brand, Distributed by Sysco Corporation, Houston, TX.
5096342 Imperial Blue Lake cut green beans, 3 sieve (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 7486512136).
5096359 Imperial Blue Lake cut green beans, 4 sieve (green beans, water, salt) in 6 lb. 5 oz. cans (UPC 7486512137).

US brand Distributed by U.S. FoodService, Columbia, MD.
Cut green beans, mixed sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 171132 (UPC 5810801048).
Fancy Blue Lake cut green beans (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 173416 (UPC 5810811195).
Fancy Blue Lake cut green beans, 3 sieve, (green beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans, 170672 (UPC 5810801040).
Fancy Blue Lake cut green beans, 4 sieve, (green beans, water, salt) 170232 in 101 oz. (6 lb. 5 oz.) cans, 170672 (UPC 5810801041).
Cut green beans, 5 Sieve, (green beans, water, salt) in 101 oz (6 lb 5 oz) cans, 170675 (UPC 5810801042).

USDA, Food and Nutrition Service, Special Nutrition Programs, Alexandria, VA label.
Cut green beans (green beans, water, salt) in 6 lb. 6 oz. cans (UPC 1500101061).
Garbanzo beans (garbanzo beans, water, salt, calcium chloride, EDTA) in 6 lb. 12 oz. cans (UPC code 1500101089).

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New Era Canning Company (Botulism) Recall Page

FDA News

FOR IMMEDIATE RELEASE
February 7, 2008

Media Inquiries:
Michael Herndon, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

New Era Canning Company Expands Nationwide Recall

Risk of botulism from additional canned vegetable products

The U.S. Food and Drug Administration (FDA) is alerting consumers, food service operators, and food retailers that New Era Canning Company, New Era, Mich., is broadening its nationwide recall of canned vegetable products for a third time because of the potential for its foods to be contaminated with *Clostridium botulinum (C. botulinum)*.

C. botulinum produces the toxin that causes botulism and can cause life-threatening illness or death. The affected New Era products are large institutional-sized cans, weighing between six and seven pounds, of various types of beans, blackeye peas, and asparagus.

To date, no illnesses have been reported to the FDA. However, consumers should not consume these products, even if they appear to be normal, because of the potential serious risk to health. Consumers who have the affected products, or who have used them in recipes, should immediately throw the cans and food away.

The potentially contaminated products are marketed under ten different brand names:

1. Classic Sysco
2. Code
3. Frosty Acres Restaurant's Pride Preferred
4. GFS
5. Kitchen Essentials
6. Monarch Heritage
7. Necco
8. New Era
9. Nugget
10. Reliance Sysco

Processors other than New Era may be packing these brands. Only products packed by New Era are subject to the recall, so individuals must check the lot numbers on the bottom of the cans to determine if the product is affected by the recall. A complete list of specific brands, products, and lot codes subject to the New Era recalls can be found at http://www.fda.gov/oc/opacom/hottopics/newera.html.

Symptoms of botulism poisoning in humans can begin from six hours to two weeks after eating food that contains the toxin. Symptoms may include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, and muscle weakness that moves progressively down the body, affecting the shoulders first, then descending to the upper arms, lower arms, thighs, and calves. Botulism poisoning also can cause paralysis of the breathing muscles, which can result in death unless assistance with breathing (mechanical ventilation) is provided. Individuals who have these symptoms and who may have recently eaten the products under recall or other food products made with them should seek immediate medical attention.

Any food that may contain the affected products should be disposed of carefully. Even tiny amounts of the *C. botulinum* toxin can cause serious illness when ingested, inhaled, or absorbed through the eye or a break in the skin. Skin contact should be avoided as much as possible, and hands should be washed immediately after handling the food.

When disposing of these products, double-bag the cans in plastic bags. Make sure the bags are tightly closed, then place in a trash receptacle for non-recyclable trash outside of the home. Restaurants and institutions should ensure that such products are only placed in locked receptacles that are not accessible to the public. Additional instructions for safe disposal may be found at www.cdc.gov/ncidod/dbmd/diseaseinfo/botulism_g.htm . Anyone with questions may call the FDA at 1-888-SAFEFOOD.

This recall is the most recent to result from an ongoing investigation of New Era Canning's processing plant by the FDA and the Michigan Department of Agriculture. The FDA initiated an inspection of New Era Canning, along with inspections of other low acid canned food manufacturers, following four cases of botulism in consumers who had consumed canned, hot dog chili sauce in the summer of 2007.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

New Era Canning Company Announces New Nationwide Recall of Vegetable Products in #10 cans (6 to 7 pound cans)

Contact:
Linda Miller
1-800-282-9007 Ext 111

FOR IMMEDIATE RELEASE -- New Era, MI -- February 7, 2008 --- New Era Canning Company of New Era, Michigan is recalling all cans of vegetable products in #10 cans (large cans containing between 6 and 7 pounds) on the list below because they may have been processed under conditions which could have led to contamination by *Clostridium botulinum* bacterium spores, which can cause life-threatening illness or death.

While the UPC on the can label may be helpful in determining whether the product might be under recall, **customers will need to also examine the lot code information on the can end to determine whether the can is subject to recall**, as some distributors may purchase these products from more than one supplier. The UPC and lot code information has been included on the product list for each product under recall to make the identification of any recalled products easier.

Clostridium botulinum bacterium spores have the potential for growth that produces a toxin that causes a potentially fatal form of food poisoning - botulism. Symptoms of botulism poisoning in humans can begin from 6 hours to 2 weeks after eating food that contains the toxin. Symptoms may include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, and muscle weakness that moves progressively down the body, affecting the shoulders first, then descending to the upper arms, lower arms, thighs, and calves. Botulism poisoning also can cause paralysis of the breathing muscles, which can result in death unless assistance with breathing (mechanical ventilation) is provided. Individuals who have these symptoms and who may have recently eaten the any of the recalled vegetable products currently under recall or other food products made with these items should seek immediate medical attention.

The issues were uncovered in a FDA inspection of products that were in the company's possession. NO product has tested positive for the toxin and there have been NO cases of botulism reported from these products.

This recall only affects the products in the large #10 cans, the majority of which were potentially sold nationwide to various food service customers. However these products may also have been purchased by consumers at retail stores. The code on the cans may be embossed (stamped into the metal of the can) or printed in ink on one of the metal can ends and the first set of numbers or letters in the code may be used to identify whether the product was canned by New Era Canning. We have been alerted that some of our cans may be missing the can codes. Any cans of these products without a code should not be opened or used and assumed to be under the recall.

Examples of how a lot code may appear on a can of Green Beans, Italian Cut are: "00249 2BH7FL", "00249 1515 2BH7FL", "ITAL 2BH7FL" or "ITAL 1515 2BH7FL". (These are not necessarily actual can codes). In these examples, the "00249" and the "ITAL", being the first set of numbers or letters in the lot code, would be used to identify that the product was canned by New Era Canning.

Examples of how a lot code may appear on a can of Great Northern beans are: "00249 34F7LG", "00249 1515 34F7LG", "NORTH 34F7LG" or "NORTH 1515 34F7LG". (These are not necessarily actual can codes). In these examples, the "00249" and the "NORTH", being the first set of numbers or letters in the lot code, would be used to identify that the product was canned by New Era Canning.

New Era Canning, in conjunction with the US Food and Drug Administration and the Michigan Department of Agriculture, is thoroughly evaluating all processes and procedures to determine the cause of the problem.

Any food that may be contaminated should be disposed of carefully. Even tiny amounts of toxins ingested,

inhaled, or absorbed through the eye or a break in the skin can cause serious illness. Skin contact should be avoided as much as possible, and the hands should be washed immediately after handling the food. Customers who have these products or any foods made with these products should throw them away immediately. Double bag the cans in plastic bags that are tightly closed, then place in a trash receptacle for non-recyclable trash outside of the home. Restaurants and institutions are encouraged to assure that such products are only placed in locked receptacles which are not accessible to the public. Additional instructions for safe disposal can be found at www.cdc.gov/botulism/botulism_faq.htm. Anyone with questions can call FDA at 1-888-SAFEFOOD.
Customers with questions may contact New Era Canning at 1-800-282-9007 Ext. 111.

The following products are affected by this recall action:

Classic Sysco brand, Distributed by Sysco Corporation, Houston, TX.

Green asparagus cuts & tips (asparagus, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 7486510471). All lot codes beginning with "00249" are included.

Great Northern beans (Great Northern beans, water, salt, calcium chloride, EDTA) in 108 oz. (6 lb. 12 oz.) cans (UPC 7486510486). All lot codes beginning with "00249" or "NORTH" are included.

Green beans, Italian cut, (Italian green beans, water, salt), in 105 oz. (6 lb. 9 oz.) cans (UPC 7486511294). All lot codes beginning with "00249" or "ITAL" are included.

Light red kidney beans (kidney beans, water, corn sweetener, salt, calcium chloride, EDTA) in 108 oz. (6 lb. 12 oz.) cans (UPC 7486510642). All lot codes beginning with "00249" or "LRKID" are included.

Red beans (red beans, water, salt, calcium chloride, EDTA) in 110 oz. (6 lb. 14 oz.) cans (UPC 7486510638). All lot codes beginning with "00249" or "RED" are included.

Cut wax beans (wax beans, water, salt) in 101 oz. (6 lb. 5 oz.) cans (UPC 7486511434). All lot codes beginning with "00249" or "WAX" are included.

Code brand, Distributed by Code, Atlanta, GA.

Dark red kidney beans (soaked kidney beans, water, corn sweetener, salt, calcium chloride, EDTA) in 6 lb. 12 oz. cans (UPC 1207316042). All lot codes beginning with "00249" or "DRKID" are included.

Fancy cut wax beans 4 sieve (wax beans, water, salt) in 6 lb. 5 oz. cans (UPC 1207310183). All lot codes beginning with "00249" or "WAX" are included.

Frosty Acres Restaurant's Pride Preferred brand, Packed for F.A.B., Inc., Alpharetta, GA.

Black beans (cooked black beans, water, ferrous gluconate, calcium chloride) in 6 lb. 15 oz. cans (UPC 4820049145). All lot codes beginning with "00249" or "BLACK" are included.

Blackeye Peas (Blackeye peas, water, salt, calcium chloride, EDTA) in 6 lb. 12 oz. cans (UPC 4820049146). All lot codes beginning with "00249" or "BEP" are included.

Fancy Great Northern beans (Great Northern white beans, water, salt, natural flavors and calcium chloride) in 110 oz. (6 lb. 14 oz.) cans (UPC 4820068288). All lot codes beginning with "00249" or "NORTH" are included.

Fancy cut Italian green beans (Italian beans, water, salt) in 105 oz. (6 lb. 9 oz.) cans (UPC 4820068390). All lot codes beginning with "00249" or "ITAL" are included.

Fancy dark red kidney beans (dark red kidney beans, water, corn syrup, salt, calcium chloride) in 111 oz. (6 lb. 15 oz.) cans (UPC 4820068171). All lot codes beginning with "00249" or "DRKID" are included.

Fancy Mexican style chili beans (white beans, water, corn syrup, sugar, tomato paste, salt, dextrose, onion powder, garlic powder, oleoresin paprika, natural flavors) in 111 oz. (6 lb. 15 oz.) cans (UPC 4820068534). All lot codes beginning with "00249" or "CHILI" are included.

Fancy pinto beans (pinto beans, water, salt, calcium chloride, EDTA) in 111 oz. (6 lb. 15 oz.) cans (UPC 4820068939). All lot codes beginning with "00249" or "PINTO" are included.

Fancy red beans (prepared red beans, water, salt, calcium chloride, EDTA) in 6 lb. 12 oz. cans (UPC 4820069023). All lot codes beginning with "00249" or "RED" are included.

Fancy vegetarian beans in tomato sauce (white beans, water, corn syrup, sugar, tomato paste, salt, dextrose, onion powder, garlic powder, oleoresin paprika and natural flavorings) in 112 oz (7 lb.) cans (UPC 4820069161). All lot codes beginning with "00249" or "VEG" are included.

GFS brand, Distributed by Gordon Food Service, Grand Rapids, MI

Fancy all green asparagus cuts & tips (asparagus, water, salt) in 6 lb. 5 oz. cans, reorder no. 229601 (UPC 9390122960). All lot codes beginning with "00249" are included.

Fancy black beans (black beans, water, salt) in 6 lb. 12 oz. cans, reorder no. 557714 (UPC 9390155771). All lot codes beginning with "00249" or "BLACK" are included.

Italian cut green beans (Italian green beans, water, salt) in 6 lb. 9 oz. cans, reorder no. 769878 (UPC 9390176987). All lot codes beginning with "00249" or "ITAL" are included.

Medium lima beans (lima beans, water, salt) in 6 lb. 12 oz. cans, reorder no. 118796 (UPC 9390111879). All lot codes beginning with "00249" or "LIMA" are included.

Fancy Mexican style chili beans (soaked red beans, water, chili seasoning, salt, corn starch, tomato paste, sugar, calcium chloride) in 6 lb. 12 oz. cans, reorder no. 192015 (UPC 9390119201). All lot codes beginning with "00249" or "CHILI" are included.

Fancy cut wax beans 4 sieve (wax beans, water, salt) in 6 lb. 5 oz. cans, 118834 (UPC 9390111883). All lot codes beginning with "00249" or "WAX" are included.

Kitchen Essentials brand, Distributed by Gordon Food Service, Grand Rapids, MI.

Cut wax beans mixed sieve (wax beans, water, salt) in 6 lb. 5 oz. cans, 274453 (UPC 9390127445). All lot codes beginning with "00249" or "WAX" are included.

Monarch Heritage brand, Packed for PYA/Monarch, Inc, Greenville, SC.

Italian style cut green beans (green beans, water, salt) in 6 lb. 5 oz. cans, 173865 (No UPC code). All lot codes beginning with "00249" or "ITAL" are included.

Necco brand, Packed by New Era Canning Company, New Era, MI.

Cut wax beans (wax beans, water, salt) in 6 lb. 6 oz. cans (UPC 3683513440). All lot codes beginning with "00249" or "WAX" are included.

New Era brand, Distributed by New Era Canning Co, New Era, MI.

Asparagus cuts & spears (asparagus, water, salt) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511220). All lot codes beginning with "00249" are included.

Black beans (black beans, water, salt) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511692). All lot codes beginning with "00249" or "BLACK" are included.

Black-eyed peas (black-eye peas, water, salt, calcium chloride, EDTA) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511698). All lot codes beginning with "00249" or "BEP" are included.

Butter beans (lima beans, water, salt, sugar, calcium chloride, EDTA) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511694). All lot codes beginning with "00249" or "LIMA" are included.

Chili beans in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511675). All lot codes beginning with "00249" or "CHILI" are included.

Great Northern beans (Great Northern beans, water, salt, calcium chloride, EDTA) in 110 oz. (6 lb. 14 oz.) cans (UPC 3683511688). All lot codes beginning with "00249" or "NORTH" are included.

Italian Cut Green Beans (Italian beans, water, salt) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511342). All lot codes beginning with "00249" or "ITAL" are included.

Light red kidney beans, (kidney beans, water, corn sweetener, salt, calcium chloride, EDTA) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511682). All lot codes beginning with "00249" or "LRKID" are included.

Dark red kidney beans, (kidney beans, water, corn sweetener, salt, calcium chloride, EDTA) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511680). All lot codes beginning with "00249" or "DRKID" are included.

Lima beans (lima beans, water, salt) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511696). All lot codes beginning with "00249" or "LIMA" are included.

Pinto beans (pinto beans, water, salt, calcium chloride, EDTA) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511686). All lot codes beginning with "00249" or "PINTO" are included.

Red beans (red beans, water, salt) in 6 lb. 12 oz. cans (no UPC). All lot codes beginning with "00249" or "RED" are included.

Vegetarian beans (white beans, water, cane syrup, tomato paste, corn syrup, salt, vinegar, calcium chloride, onion powder, paprika, spice, natural flavorings) in 108 oz. (6 lb. 12 oz.) cans (UPC 3683511670). All lot codes beginning with "00249" or "VEG" are included.

Cut wax beans (wax beans, water, salt) in 102 oz. (6 lb. 6 oz.) cans (UPC 3683511440). All lot codes beginning with "00249" or "WAX" are included.

Nugget brand, Distributed by Nugget, Atlanta, GA.

Asparagus cuts & tips (asparagus, water, salt) in 6 lb. 12 oz. cans, (UPC 4410503580). All lot codes beginning with "00249" are included.

Reliance Sysco, Distributed by Sysco Corporation, Houston, TX.

Cut wax beans 4 sieve (wax beans, water, salt) in 6 lb. 5 oz. cans, 4108056 (UPC 7486512190). All lot codes beginning with "00249" or "WAX" are included.

Wax beans mixed and short cuts (wax beans, water, salt) in 6 lb. 5 oz. cans, 4182788 (UPC 7486512231). All lot codes beginning with "00249" or "WAX" are included.

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New Era Canning Company (Botulism) Recall Page

FDA Press Release *(Feb. 7, 2007)*

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New Era Canning Issues Vegetable Recall Amid Botulism Fears

Date Published: Friday, February 8th, 2008

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The New Era Canning Company is issuing yet another **botulism** recall, the fourth since late December. This time, New Era of New Era, Michigan is recalling all cans of vegetable products in #10 cans—large cans containing between six and seven pounds—which may have been processed under conditions which could have led to contamination by Clostridium botulinum, the bacterial that causes botulism, a possibly life-threatening illness.

Botulism is a rare but serious paralytic illness caused by a nerve toxin produced by that bacterium. The classic symptoms of food-borne botulism include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness. Infants appear lethargic, feed poorly, are constipated, have a weak cry, and poor muscle tone. These symptoms are indicative of the muscle paralysis caused by the bacterial toxin; left untreated, symptoms may progress to cause paralysis of the arms, legs, trunk, and respiratory muscles. Symptoms generally begin 18 to 36 hours after eating contaminated food, but can occur as early as six hours or as late as 10 days. The respiratory failure and paralysis that occur with severe botulism may require a patient to be placed on a ventilator for weeks; however, if diagnosed early, botulism can be treated with an antitoxin. While this can prevent patients from worsening, recovery still takes weeks. Also, physicians may try to remove contaminated food still in the stomach by either inducing vomiting or administering enemas.

According to the **New Era vegetable recall notice** issued by the Food & Drug Administrion,w hile the UPC code on the can label may be helpful, customers must examine the lot code on the can and to determine whether the can is subject to recall since some distributors may purchase these products from multiple suppliers. The majority of these products were sold nationwide to food service customers; however, some may have been purchased by consumers. The can codes may be embossed or printed on one of the can ends; some cans may be missing codes and should be assumed to be under the recall. Anyone with questions can call the FDA at 1-888-SAFEFOOD; customers may contact New Era Canning at 1-800-282-9007 Ext. 111.

The issues were discovered in an FDA inspection. No product has tested positive and there have been no reports of botulism reported. New Era, with the FDA and the Michigan Department of Agriculture, is evaluating processes and procedures to determine the cause.

The FDA is advising customers to throw contaminated cans and food away immediately and carefully. Even small amounts of the toxin ingested, inhaled, or absorbed through the eye or a break in the skin can cause serious illness; skin contact should be avoided and hands should be washed immediately after handling the food. When disposing of the tainted food, double-bag the cans in plastic bags, ensure the bags are tightly closed, and place the bags in a trash receptacle for non-recyclable trash outside the home. Restaurants and institutions should ensure the products are placed in locked receptacles not accessible to the public.

This is the fourth recall issued by New Era Canning in less than two months. The New Era Canning botulism recalls started in December, when the company recalled 1,026 cans of green beans.

This entry was posted on Friday, February 8th, 2008 at 7:12 am and is filed under Legal News, Food Poisoning, Botulism.

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IA #16-131, 8/3/07, IMPORT ALERT #16-131, "DETENTION WITHOUT PHYSICAL EXAMINATION OF AQUACULTURED CATFISH, BASA (Pangasius sp), SHRIMP, DACE, AND EEL PRODUCTS FROM THE PEOPLE'S REPUBLIC OF CHINA DUE TO THE PRESENCE OF NEW ANIMAL DRUGS AND/OR UNSAFE FOOD ADDITIVES", ATTACHMENT 9/18/07

NOTE: This revision includes additional sampling guidance. Changes are bracketed by asterisks.

TYPE OF ALERT: DETENTION WITHOUT PHYSICAL EXAMINATION (DWPE)

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

PRODUCT: Aquacultured seafood products

PRODUCT CODE:

Catfish (Ichtalurus sp.)
16X[][]02
16A[][]10, 16B[][]10, 16C[][]10, 16I[][]10, 16S[][]10
16A[][]67, 16B[][]67, 16C[][]67, 16I[][]67, 16S[][]67

Shrimp
16X[][]21
16J[][]05, 16K[][]05, 16L[][]05

Basa (Pangasius sp.)
16X[][]43
16A[][]82, 16B[][]82, 16C[][]82, 16I[][]82, 16S[][]82

Dace - 16A[][]57, 16B[][]57, 16C[][]57, 16I[][]57, 16S[][]57

Eel - 16A[][]15, 16B[][]15, 16C[][]15, 16I[][]15, 16S[][]15

Aquaculture Harvested Fishery/Seafood Products, N.E.C.
16X[][]99

(*Dace and eel may also be coded as aquaculture harvested product, N.E.C.; i.e. 16X[][]99)

PROBLEM: Unapproved drug residues

Unsafe food additives

PAF: ANT (Drug residues)
FAD (Food Additive)

PAC: 04018

COUNTRY: China, People's Republic of (CN)

MANUFACTURER FEI#: All

IMPORTER'S ID#: N/A

CHARGES: "The article is subject to refusal of admission pursuant to Section 801(a)(3), in that it appears to bear or contain a food additive that is unsafe within the meaning of Section 409 [Adulteration, Section 402(a)(2)(C)(i)]."
(OASIS CHARGE CODES: UNSAFE ADD)

AND/OR

"The article is subject to refusal of admission pursuant to Section 801(a)(3), in that it appears to bear or contain a new animal drug (or conversion product thereof) that is unsafe within the meaning of Section 512 [Adulteration, Section 402(a)(2)(C)(ii)]."
(OASIS CHARGE CODES: VETDRUGRES)

RECOMMENDING OFFICE: OFS/DSS, HFS-325
OC/DE, HFS-606

REASON FOR ALERT: There has been extensive commercialization and increased consumption of aquaculture seafood products worldwide. Aquacultured seafood has become the fastest growing sector of the world food economy, accounting for approximately half of all seafood production worldwide. Approximately 80% of the seafood consumed in the U.S. is imported from approximately 62 countries. Over 40% of that seafood comes from aquaculture operations. As the aquaculture industry continues to grow and compete with wild-caught seafood products, concerns regarding the use of unapproved animal

drugs and unsafe chemicals and the misuse of animal drugs in aquaculture operations have increased substantially.

China is the largest producer of aquacultured seafood in the world, accounting for 70% of the total production and 55% of the total value of aquacultured seafood exported around the world. China is currently the third largest exporter of seafood to the U.S. Shrimp and catfish products represent two of the top ten most consumed seafood products in the U.S.

The use of unapproved antibiotics or chemicals in aquaculture raises significant public health concerns. There is clear scientific evidence that the use of antibiotics or chemicals, such as malachite green, nitrofurans, fluoroquinolones, and gentian violet during the various stages of aquaculture can result in the presence of residues of the parent compound or its metabolites in the edible portion of the aquacultured seafood. The presence of antibiotic residues may contribute to an increase of antimicrobial resistance in human pathogens. Moreover, prolonged exposure to nitrofurans, malachite green, and gentian violet has been shown to have a carcinogenic affect.

In the United States, use of malachite green, nitrofurans, fluoroquinolones, or gentian violet as drugs in food-producing animals would require an approved new animal drug application under Section 512 of the Federal Food, Drug, and Cosmetic Act (FFDCA). FDA has not approved these antibiotics for use as drugs in aquacultured animals. Therefore, if they are used in aquaculture with an intent that they treat disease in, or affect the structure or function of, any aquacultured animal, they are considered to be unsafe new animal drugs within the meaning of Section 512, and the presence of their residues in seafood adulterates the seafood under 402(a)(2)(C)(ii) of the FFDCA.

Furthermore, malachite green, nitrofurans, fluoroquinolones and gentian violet are not generally recognized as safe under any conditions of intended use that may reasonably be expected to result in their becoming a component of food. Therefore, if intended for any such use, they are unsafe food additives within the meaning of section 409 of the FDCA and would render the food adulterated under section 402(a)(2)(C)(i).

FDA has several existing Import alerts related to unapproved drugs in seafood dating back to November of 2001 (IA #16-124 DWPE of Seafood Products Due to Unapproved Drugs, IA #16-129 DWPE of Seafood Products Due to Nitrofurans, and IA #16-130 DWPE of Eel from China Due to the presence of Malachite Green). Based on an increased monitoring of imported aquacultured seafood from October 1, 2006, through May 31, 2007, FDA continued to find residues of unapproved new animal drugs and/or unsafe food additives in seafood imported from China. During that period, FDA tested 89 samples consisting of catfish, Basa, shrimp, dace and eel from China. Twenty two (22) of the 89 samples (25%) were found to contain drug residues. These residues include nitrofurans detected in shrimp at levels above 1 ppb; malachite green detected in dace, eel and catfish/Basa fish at levels ranging from 2.1 to 122 ppb; gentian violet detected in eel and catfish at levels ranging from 2.5 ppb to 26.9 ppb and fluoroquinolones in catfish/Basa at level ranging from 1.9 to 6.5 ppb. Furthermore, Chinese authorities have acknowledged permitting the use of fluoroquinolones in aquaculture

Although the use of some animal drugs (nitrofurans and malachite green) in aquaculture has been prohibited by Chinese authorities since 2002, FDA continues to find residues of these and other animal drugs in shipments of aquacultured seafood products from China.

GUIDANCE: Districts may detain without physical examination, all shipments of aquacultured catfish, Basa (Pangasius sp), shrimp, dace, and eel from the People's Republic of China (CN) except for the firms identified on the attachment to this alert.

Screening criteria has been set into OASIS.

If a firm, shipper, or importer believes that their product should not be subject to detention under this import alert they should forward information supporting their position to FDA at the following address:

Food and Drug Administration
Division of Import Operations and Policy (HFC-170)
5600 Fishers Lane, Room 12-36

Rockville, MD 20587

In order to secure release of an individual shipment subject to this Import Alert, the importer should provide the results of a third-party laboratory analysis of a representative sample of the lot verifying that products do not contain malachite green and its metabolite leucomalachite green, nitrofurans, gentian violet, leucogentian violet or fluoroquinolones. The chart provided below identifies which residues should be screened for each species.

Third-party laboratories may use any methods that are found acceptable to FDA. (e.g., see http://www.cfsan.fda.gov/seafood1.html

The following residues should be tested for each species.

SPECIES	RESIDUE
Catfish, Basa, and Other Pangasius	Malachite Green Fluoroquinolones Gentian Violet
Shrimp	Malachite Green Fluoroquinolones Nitrofurans Gentian Violet
Dace	Malachite Green Gentian Violet
Eel	Malachite Green Gentian Violet

*** NOTE: The samples taken should be representative of the shipment. The following provides guidance on what may be considered a representative sample.

Import sampling plan

Single product type entry

Shrimp The sample should consist of a minimum of 12 sub-samples. When an entry consists of multiple

lines of similar products (e.g., multiple sizes of headless shrimp), the sample should be representative of the entire entry and should be collected across all lines, with a minimum of two sub-samples per line. The sampling should be proportional based on the quantity of product (e.g. more sub-samples should be obtained from larger lines, fewer sub-samples from smaller lines). Obtaining 12 sub-samples from a single line or a limited number of lines when multiple lines of similar products are offered for the entry will not provide a representative sample for that entry.

If an entry contains only one line of aquacultured product, then a minimum of 12 sub-samples should be obtained from that single line. If the entry includes multiple date codes, the sample should reflect a range of date codes (e.g., all sub-samples should not be collected from a single date code).

Each sample should consist of 12 sub-samples, minimum 225g (0.5 lb.) per sub-sample, total 2.7 kg (6.0 lb.) of product. If the product unit size is larger than 225g (0.5 lb.) and less than or equal to 3 lb., collect one product unit per sub-sample. If the unit size is less than 225g. (0.5 lb.), collect an adequate number of units so that the amount collected per sub-sample equals a minimum of 225 grams (0.5 lb.).

For units (block frozen) larger than 3 lbs. only: If the units must be sampled and shipped intact, collect 6 sub-samples (units). Alternatively, sub-samples of at least 225g (0.5 lb.) may be broken/sawed off (keep frozen) from each of 12 units, and the twelve (12) 225 g sub-samples shipped to the analyzing lab.

Analysis for Nitrofuran should be conducted on individual subsamples.

Analyses for all other residues should be conducted on a composite sample.

Catfish, Basa, Dace, Eel

The sample should consist of a minimum of 12 sub-samples and be representative of the entry. If the entry contains multiple lines, each line should be sampled separately. A sample, consisting of a minimum of 12 sub-samples, should be collected from each line. If the entry consists of multiple date codes, the samples should be representative of a range of date codes. Analyses should be conducted on a composite sample from each line.

Each sample should consist of a minimum of 12/225 gram (0.5 lb.) sub-samples, totaling 2.7 kg (6.0 lb.) of product. If the container size is larger than 225 grams (0.5 lb.), collect one container per sub-sample. If the container is less than 225 grams (0.5 lb.), collect an adequate number of containers so that the amount collected per sub-sample equals a minimum of 225 grams (0.5 lb.).

Mixed products entry

If the entry consists of mixed aquacultured seafood products, a minimum of 12 sub-samples should be obtained from each line. For example, if an entry includes one line of headless shrimp and one line of basa fillets, two samples should be obtained one sample, consisting of a minimum of 12 sub-samples, of shrimp; and one sample, consisting of a minimum of 12 sub-samples, of basa.

Analyses should be conducted on a sample from each line as described above, depending on the commodity.***

Sample Preparation

Prepare one composite from an equal amount of each subsample for the testing of malachite green, fluoroquinolones, and gentian violet.

Shrimp are to be analyzed on an individual sub basis for nitrofurans. When sampling guidance directs the collection of six subsamples, two portions from each of the six subsamples should be individually analyzed. ***

For questions or issues concerning science, science policy, analysis, preparation, or analytical methodology, contact the Division of Field Science at (301) 827-7605.

In order to remove a firm from detention without physical examination, information should be provided to FDA to adequately assess whether a manufacturer has the appropriate controls and processes in place to ensure the quality of the product, the firm or shipper should provide the following information (In English):

1) Documentation showing that a minimum of five (5) consecutive entries have been released by FDA based on third-party laboratory analysis of a representative sample of the lot verifying that products do not contain malachite green and its metabolite leucomalachite green, nitrofurans, gentian violet, leucogentian violet and fluoroquinolones. The chart provided above identifies which residues should be screened for each species. Third-party laboratory must use methods acceptable to FDA (e.g., see http://www.cfsan.fda.gov/seafood1.html);

and

2) Documentation, from an appropriate third-party (e.g. a government inspection authority such as AQSIQ) demonstrating that an inspection of the processor was conducted and that the seafood was processed in accordance with FDA's Seafood HACCP regulations, 21 CFR part 123, including controls for aquaculture drugs. See 21 CFR 123.12(a).

Documentation should include test results of any products sampled during the course of the inspection, demonstrating that the products do not contain malachite green or its metabolite leucomalachite green, nitrofurans, gentian violet, leucogentian violet or fluoroquinolones.

and

3) Documentation that the processor is in compliance with all Chinese government requirements for exporting aquacultured seafood to the U.S.

Documentation should include copies of any registration that may be required by the Chinese government.

All requests for removal (exemption) from DWPE will be forwarded by DIOP to CFSAN (HFS-606) for evaluation.

PRIORITIZATION GUIDANCE: I

FOI: No purging required

KEYWORDS: Nitrofurans, Fluoroquinolones (ciprofloxacin and enrofloxacin), malachite green, leucomalachite green, gentian violet, aquaculture,

PREPARED BY: Barbara Montwill, CFSAN/OFS/DSS/SAPB (HFS-325), 301-436-1426
Giselle Jordan, CFSAN/OC/DE/PAB (HFS-606), 301-436-1576
Ted Poplawski, DIOP, (301) 443-6553

REVISED BY: Virginia L. Meeks, DIOP, (301) 594-3845

DATE LOADED INTO FIARS: August 3, 2007

ATTACHMENT TO IMPORT ALERT #16-131 9/18/07

Firms and products exempt from DWPE recommendation

FIRM	PRODUCT/PRODUCT CODE
Zhangjiang Guolian Aquatic Products Co., Ltd. 6 Yongping S. Rd. Pingle Industry Development Region Zhangjiang, Guangdong, China FEI# 3004097215	Shrimp 16J[][]05/16K[][]05 16L[][]05/16X[][]21 9/18/07

washingtonpost.com

FDA Investigates Import Seafood Claims

By JUSTIN PRITCHARD
The Associated Press
Thursday, August 9, 2007; 12:36 AM

LOS ANGELES -- The Food and Drug Administration said Wednesday it is checking whether shipments of Chinese seafood on an agency watch list were properly cleared for public consumption without being tested for banned drugs or chemicals.

Agency officials said that while they believe the shipments were screened correctly, they wanted more details. That review comes in response to findings The Associated Press published Tuesday that at least 1 million pounds of frozen shrimp, catfish or eel raised in Chinese ponds were on an agency watch list but were not diverted to a lab.

The 28 shipments the AP identified arrived under an FDA "import alert," which is supposed to trigger the tough screening requirement.

The seafood, equal to the amount 66,000 Americans eat in a year, did not pose an immediate public health risk; the FDA has worried that long-term exposure to substances fed to some Chinese seafood could increase the risk of cancer or make antibiotics less potent.

A leading Democrat in the House of Representatives said the AP's report raises serious questions about FDA's inspection system and his committee's investigators want the FDA to explain what percentage of all import alert shipments from China _ not just seafood _ are being stopped and tested.

"The discovery that suspect seafood from China has reached dining room tables in America without being tested is disturbing," said Rep. John Dingell, D-Mich., whose Energy and Commerce Committee has been investigating the FDA's imported-food safety record. "Apparently, the 'import alert' system used by the FDA to test high risk foods cannot be trusted."

The agency said it has about 450 budgeted positions for screening all the imports it oversees _ approximately 20 million shipments of everything from fish to vegetables to pharmaceuticals. Funding for inspectors has not kept pace with the surge in imports over the past decade and FDA employees have told Dingell's committee they're too stretched to guarantee food safety.

For its investigation, the AP reviewed 4,300 seafood shipments from China and found 211 that arrived under import alert between October and May. It was during that period the FDA was putting specific Chinese companies with seafood that had flunked lab tests on its watch list, leading up to a June announcement that all farm-raised shrimp, catfish and eel had to be inspected.

The AP was able to reach importers that brought in 112 of the shipments. They said that 28 of the 112 shipments had not been detained and tested.

The FDA did not verify the AP's numbers.

Agency officials said their initial research showed that from an AP-provided list of more than 200 shipments that arrived under an import alert, 19 were flagged by FDA's computer system and reviewed

by a person who determined they didn't need to be tested. Agency officials said they needed to talk to local offices that processed the cargo to find out why those shipments, as well as four others, were allowed through.

The AP gave the FDA its list weeks before publication; the agency did not comment on the specific shipments until after Tuesday's story ran.

"What we're saying is that based on the electronic 30,000-foot view, we can't determine why they were released and we're going to look into those further," said Michael Chappell, the official responsible for field inspections and labs.

"There is no evidence to say they were released ... incorrectly," said Domenic Veneziano, who oversees FDA's import operations.

The agency would not provide details on the total 23 shipments without a Freedom of Information Act request.

The New York Times
nytimes.com

December 15, 2007

In China, Farming Fish in Toxic Waters

By DAVID BARBOZA

FUQING, China — Here in southern China, beneath the looming mountains of Fujian Province, lie dozens of enormous ponds filled with murky brown water and teeming with eels, shrimp and tilapia, much of it destined for markets in Japan and the West.

Fuqing is one of the centers of a booming industry that over two decades has transformed this country into the biggest producer and exporter of seafood in the world, and the fastest-growing supplier to the United States.

But that growth is threatened by the two most glaring environmental weaknesses in China: acute water shortages and water supplies contaminated by sewage, industrial waste and agricultural runoff that includes pesticides. The fish farms, in turn, are discharging wastewater that further pollutes the water supply.

"Our waters here are filthy," said Ye Chao, an eel and shrimp farmer who has 20 giant ponds in western Fuqing. "There are simply too many aquaculture farms in this area. They're all discharging water here, fouling up other farms."

Farmers have coped with the toxic waters by mixing illegal veterinary drugs and pesticides into fish feed, which helps keep their stocks alive yet leaves poisonous and carcinogenic residues in seafood, posing health threats to consumers.

Environmental degradation, in other words, has become a food safety problem, and scientists say the long-term risks of consuming contaminated seafood could lead to higher rates of cancer and liver disease and other afflictions.

No one is more vulnerable to these health risks than the Chinese, because most of the seafood in China stays at home. But foreign importers are also worried. In recent years, the European Union and Japan have imposed temporary bans on Chinese seafood because of illegal drug residues. The United States blocked imports of several types of fish this year after inspectors detected traces of illegal drugs linked to cancer.

This week, officials from the United States and China signed an agreement in Beijing to improve oversight of Chinese fish farms as part of a larger deal on food and drug safety.

Yet regulators in both countries are struggling to keep contaminated seafood out of the market. China has shut down seafood companies accused of violating the law and blacklisted others, while United States regulators are concentrating on Chinese seafood for special inspections.

Fuqing (pronounced foo-CHING) is at the top of the list this year for refused shipments of seafood from

China, with 43 rejections through November, according to records kept by the United States Food and Drug Administration. All of those rejections involved the use of illegal veterinary drugs.

By comparison, Thailand, also a major exporter of seafood to the United States, had only two refusals related to illegal veterinary drugs. China as a whole had 210 refusals for illegal drugs.

"For 50 years," said Wang Wu, a professor at Shanghai Fisheries University, "we've blindly emphasized economic growth. The only pursuit has been G.D.P., and now we can see that the water turns dirty and the seafood gets dangerous. Every year, there are food safety and environmental pollution accidents."

Environmental problems plaguing seafood would appear to be a bad omen for the industry. But with fish stocks in the oceans steadily declining and global demand for seafood soaring, farmed seafood, or aquaculture, is the future. And no country does more of it than China, which produced about 115 billion pounds of seafood last year.

China produces about 70 percent of the farmed fish in the world, harvested at thousands of giant factory-style farms that extend along the entire eastern seaboard of the country. Farmers mass-produce seafood just offshore, but mostly on land, and in lakes, ponds, rivers and reservoirs, or in huge rectangular fish ponds dug into the earth.

"They'll be a major supplier not just to the U.S., but to the world," said Richard Stavis, the chairman of Stavis Seafoods, an American company that imports Chinese catfish, tilapia and frog legs.

China began emerging as a seafood power in the 1990s as rapid economic growth became the top priority in the country. But environmental experts say that headlong pursuit of higher gross domestic product has devastated Chinese water quality and endangered the country's food supply. In Guangdong Province in southern China, fish contaminated with toxic chemicals like DDT are already creating health problems.

"There are heavy metals, mercury and flame retardants in fish samples we've tested," said Ming Hung Wong, a professor of biology at Hong Kong Baptist University. "We've got to stop the pollutants entering the food system."

More than half of the rivers in China are too polluted to serve as a source of drinking water. The biggest lakes in the country regularly succumb to harmful algal blooms. Seafood producers are part of the problem, environmental experts say. Enormous aquaculture farms concentrate fish waste, pesticides and veterinary drugs in their ponds and discharge the contaminated water into rivers, streams and coastal areas, often with no treatment.

"Water is the biggest problem in China," said Peter Leedham, the business manager at Sino Analytica, an independent food safety testing firm that works with companies that buy from China. "But my feeling is China will deal with it, because it has to. It just won't be a quick process."

Fishing for Prosperity

Fuqing is called qiaoxiang, or home, for those who go overseas, because for decades this port city on the East

China Sea is where thousands of people fled as stowaways.

In the 1980s, some emigrants began sending home money and ideas at just about the time that investors were arriving from Japan and Taiwan, promising to help the country build fish farms.

"Aquaculture was popular in Japan, so I saw the future," said Wang Weifu, a longtime eel producer.

Thousands of peasants who had struggled to earn a living harvesting rice and potatoes began carving up huge plots, digging rectangular pits and filling them with water to create fish ponds. Other parts of the country followed, creating fish farms alongside roads, near rivers and streams and in big lakes, ponds and reservoirs.

Today, the mighty Yangtze River is lined with fish farms. Historic Lake Tai is stocked with crab pens. Near Ningde, 90 miles north of here, thousands of people live in a huge bay area, where they float on large wooden rafts, feeding and harvesting caged fish, like the yellow croaker.

The government hoped the building boom would lift millions out of poverty. And it did. There are now more than 4.5 million fish farmers in China, according to the Fishery Bureau.

Lin Bingui, 50, is one of them, a former bricklayer with an easy smile who now manages 20 enormous shrimp and eel ponds in western Fuqing, on reclaimed land with access to a narrow strait of seawater.

"This doesn't take a lot of technology," he said while walking into an indoor pond, where he raises baby eels. "You just learn it as you go along."

The boom did more than create jobs. It made China the only country that produced more seafood from fish farms than from the sea. It also helped feed an increasingly prosperous population, a longstanding challenge in China.

Many growers here struck it rich as well, people like Lin Sunbao, whose 25-year-old son is now studying at Cambridge University in England. "My best years were 1992, '93, '94," he said. "I only had one aqua farm, and I earned over $500,000 a year."

As early as the mid-1990s, though, serious environmental problems began to emerge after electronics and textile manufacturing plants moved into central Fuqing. Water shortages appeared in the southeastern part of the city, and some fish farmers say their water turned black.

Government records document the environmental ills in the region. The nearby Dongzhang Reservoir, a water source for agriculture and more than 700,000 people, was recently rated level 5, near the bottom of the government scale, unfit for fish farming, swimming or even contact with the human body.

The Long River, the major waterway in Fuqing, has been degraded by waste dumped by paper factories and slaughterhouses. The government this year rated large sections of the river below level 5, or so highly polluted that it is unfit for any use. And nearby coastal waters which are also heavily fish farmed are polluted with oil, lead, mercury and copper, according to the State Environmental Protection Administration in China.

As water quality in Fuqing declined, farmers who often filled their ponds with too much seafood tried to fight

off disease and calm stressed fish with an array of powerful, and often illegal, antibiotics and pesticides.

Eel producers, for example, often used nitrofuran to kill bacteria. But that antibiotic has been banned for use in animal husbandry in the United States, Europe, Japan, and even China, because it has caused cancer in laboratory rats.

Importers of Chinese seafood quickly caught on. In recent years, eel shipments to Europe, Japan and the United States have been turned back or destroyed because of residues of banned veterinary drugs. Eel shipments to Japan have dropped 50 percent through August of this year, dealing a heavy blow in Fuqing.

Chinese farmers say they have stopped using the banned medicines, and have suffered a 30 percent decline in survival rates of their fish and other seafood.

"Before 2005, we did use drugs blindly. They were very effective in fighting disease," said Wang Weifu, chairman of a local eel association, noting that drug residues might still be in the water. "But now we don't dare because of the regulations."

Some growers have lashed out at Japan, arguing that it keeps raising the drug residue standard simply to protect its own eel farms against competition. But growers here say buyers from Japan will eventually be forced to purchase eels from China.

"Our market will expand in Russia and Southeast Asia, and the E.U.," Mr. Wang said. "Also, we see big prospects in the Chinese market. In five or six years, as we transfer our export destinations, Japan will be begging us."

Retreating From the Coast

The drive about 175 miles west of Fuqing leads into the lush subtropical mountains of Fujian Province, where some of China's richest bamboo and timber reserves can be found. There, near the city of Sanming, Fuqing eel producers have built a collection of aquaculture farms, huge cement tubs wedged into the mountainside, covered by black tarps and stocked with millions of eels.

"This costs a lot more up here, but we had to do it," said Zheng Qiuzhen, a longtime Fuqing eel producer who now operates near Sanming. "We had to do something about the water problems."

In much of the country, seafood growers are leaving crowded coastal areas for less developed regions, where the land is cheaper and there is cleaner water. But they say the overall cost of doing business so far from the coast is higher, given the expense of shipping the fish in oxygenated trucks to the processing plant in Fuqing and their forswearing illegal drugs, which lowers survival rates and increases the growth period of most fish to five years from three years.

"You can't find many places as beautiful as this, covered by trees and bamboo," said Lin Sunbao, who moved from Fuqing to Sanming. "We use water from mountain streams. And because our water is better, it's harder to get disease."

This is one of the solutions to the water crisis in China: to seek out virgin territory and essentially start the

cycle all over again. And that worries scientists, who say aquaculture in China is not just a victim of water pollution but a culprit with a severe environmental legacy.

Industrial fish farming has destroyed mangrove forests in Thailand, Vietnam and China, heavily polluted waterways and radically altered the ecological balance of coastal areas, mostly through the discharge of wastewater. Aquaculture waste contains fish feces, rotting fish feed and residues of pesticides and veterinary drugs as well as other pollutants that were already mixed into the poor quality water supplied to farmers.

Besides algal blooms, some of the biggest lakes in China, like Lake Tai, are suffering from eutrophication nutrient bombs, brought on partly by aquaculture, that can kill fish by depleting the water's oxygen. The government is forcing aquaculture out of these lakes, and also away from the Long River in Fuqing.

Places like Sanming may not be pristine for long. Heavy industry is moving in, lured by mineral riches and incentives from local governments, which are pushing for development.

And Sanming already has 72 giant eel farms, producing 5,000 tons of seafood a year. Those farms together use about 280 million gallons of water a day and then discharge the wastewater the following day, back into the Sanming environs.

There are efforts to operate aquaculture in a sustainable way. In Norway, for instance, salmon producers use sophisticated technology, including underwater cameras, to monitor water quality and how much fish feed is actually consumed. But nothing like this is being done in China, and specialists like Li Sifa of Shanghai Fisheries University insist that Chinese regulations are too lax and that enforcement efforts are often feeble or nonexistent.

The government has stepped up its inspections of fish farms and seafood processing plants here, alerting workers of the dangers and consequences of using illegal drugs. But the drugs have remained a problem, partly because of poor water quality.

A possible solution to the water woes is to move aquaculture well out to sea, specialists say, with new technology that allows for deepwater fish cages served by automatic feeding machines.

The United States is already considering such a plan, partly as a way to make it less dependent on imports, which now fill 80 percent of its seafood needs. China is also considering adopting what is now being called "open ocean" aquaculture.

Currently, China's coastal fish farms face many of the same challenges as those on land. Waters there are heavily polluted by oil, lead, mercury, copper and other harsh substances. Veterinary drugs dropped in shoreline waters may easily spread to neighboring aquaculture farms and affect species outside the cages, and while coastal waters are less polluted than those on land, aquaculture farms, with their intensive production cycles, are prone to be polluters.

Still, said An Taicheng of the Chinese Academy of Sciences: "China has to go to the sea because it's getting harder and harder to find clean water. Every year there are seafood safety problems. One day, no one will dare to eat fish from dirty water, and what will farmers do?"

FDA News

Media Inquiries: 301-827-6242
Julie Zawisza
julie.zawisza@fda.hhs.gov
Catherine McDermott
catherine.mcdermott@fda.hhs.gov
Consumer Inquiries:
888-INFO-FDA

FOR IMMEDIATE RELEASE
P06-132
September 15, 2006

FDA Statement on Foodborne E.coli O157:H7 Outbreak in Spinach

Updated 9/15/06

This release was updated September 16, 2006, to remove the brand Pro*Act from the list of recalled brands. It was further updated on September 19, 2006 to remove Coastline from the list of recalled brands.

As part of the agency's continued commitment to keep the public informed of food safety issues, the Food and Drug Administration (FDA) is providing this update on the outbreak involving spinach.

The U.S. Food and Drug Administration (FDA) is continuing to alert consumers about an outbreak of *E. coli* O157:H7 in multiple states that may be associated with the consumption of fresh spinach and fresh spinach containing-products.

Based on current information, FDA advises that people not eat fresh spinach or fresh spinach containing-products that are consumed raw. Individuals who believe they may have experienced symptoms of illness after consuming pre-packaged spinach are urged to contact their health care provider.

At this time, Natural Selection Foods, LLC, of San Juan Bautista, California, is recalling all of its products that contain spinach in all the brands they pack with "Best if Used by Dates" of August 17, 2006 through October 1, 2006.

FDA continues to investigate whether other companies and brands are involved.

Natural Selection Foods, LLC brands include: Natural Selection Foods, Pride of San Juan, Earthbound Farm, Bellissima, Dole, Rave Spinach, Emeril, Sysco, O Organic, Fresh Point, River Ranch, Superior, Nature's Basket, Pro-Mark, Compliments, Trader Joe's, Ready Pac, Jansal Valley, Cheney Brothers, D'Arrigo Brothers, Green Harvest, Mann, Mills Family Farm, Premium Fresh, Snoboy, The Farmer's Market, Tanimura & Antle, President's Choice, Cross Valley, and Riverside Farms. These products include spinach and any salad with spinach in a blend, both retail and food service products. Products that do not contain spinach are not part of this recall.

E. coli O157:H7 causes diarrhea, often with bloody stools. Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called Hemolytic Uremic Syndrome (HUS). HUS is most likely to occur in young children and the elderly. The condition can lead to serious kidney damage and even death. To date, 94 cases of illness have been reported to the Centers for Disease Control and Prevention (CDC), including 14 cases of HUS and one death.

At this time, the investigation is ongoing and states that have reported illnesses to date include: California, Connecticut, Idaho, Indiana, Kentucky, Maine, Michigan, Minnesota, Nevada, New Mexico, New York, Ohio, Oregon, Pennsylvania, Tennessee, Utah, Virginia, Washington, Wisconsin, and Wyoming. The affected products were also distributed to Canada and Mexico.

FDA continues to work closely with the U.S. Centers for Disease Control and Prevention (CDC) and state and local agencies to determine the cause and scope of the problem. As part of our investigation, we will test packages of spinach from confirmed cases of *E. coli* infection.

FDA will provide daily updates on its investigation. Please check this site for updated information.

####

More Information

Recall -- State Press Release

California Department of Public Health Warns Consumers Not to Eat Fresh Ginger From China

Contact:
Suanne Buggy
(916) 440-7259

FOR IMMEDIATE RELEASE -- Sacramento, CA -- July 29, 2007 -- Dr. Mark Horton, director of the California Department of Public Health (CDPH), today warned consumers not to eat fresh ginger imported from China after the California Department of Pesticide Regulation's residue monitoring program detected the presence of aldicarb sulfoxide in some batches of imported ginger. Aldicarb sulfoxide is a pesticide that is not approved for use on ginger.

The product is known to have been distributed to Albertson's stores and Save Mart stores in northern California by Christopher Ranch of Gilroy, California.

CDPH and the U.S. Food and Drug Administration are tracing the imported ginger from the importer (Modern Trading Inc. in Alhambra, California) to determine the full distribution of the product and to identify other retail stores that may have received the product.

Currently, there are no reports of illness associated with the contaminated ginger.

Consumers who may have purchased this product from Albertson's stores and Save Mart stores in northern California should discard it.

Symptoms of aldicarb poisoning in humans are likely to occur within the first hour following exposure. Ingestion of foods contaminated with aldicarb at low levels can cause flu-like symptoms (nausea, headache, blurred vision) which disappear quickly, usually within 5 or 6 hours. However, at higher levels, ingestion of aldicarb contaminated food can also cause dizziness, salivation, excessive sweating, vomiting, diarrhea, muscle stiffness and twitching, and difficulty in breathing.

Individuals who may have consumed this product and have any of the above symptoms should contact their health care provider immediately.

####

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Metz Fresh Announces Voluntary Recall of Spinach

Contact:
Metz Fresh
831-386-1018

FOR IMMEDIATE RELEASE -- Salinas, CA -- August 28, 2007 -- Metz Fresh, LLC is voluntarily recalling bagged spinach as a result of a positive test for *Salmonella* found during routine company testing.

The spinach is distributed under the label Metz Fresh, in both retail and food service packages. These include 10 and 16 oz bags as well as 4-2.5 lb. and 4 lb. cartons. The only Metz Fresh product affected is spinach that bears the tracking codes 12208114, 12208214 and 12208314. It was distributed in the continental United States and Canada.

There have been no reports of illness or problems related to this spinach.

Salmonella is a common food borne pathogen that can cause severe illnesses, including fever, abdominal cramps and diarrhea. While most individuals recover in three to five days without medical intervention, the infection can be life-threatening to young children, the elderly and those with compromised immune systems. Consumers with any of these symptoms should call their physician.

Consumers are advised to discard this product or return it to the place of purchase for a refund. Consumers with questions about the recall should contact 831-386-1018.

"Nothing is more important to Metz Fresh than the safety of our consumers, period," said Andrew Cumming, President of Metz Fresh. "As soon as we learned of the presumptive positive test, we directed all customers to hold all boxes of the spinach affected as a precaution. Now, with this positive test confirmation, there is no question that we would recall and destroy all spinach bearing these three codes."

The positive test came during independent lab testing Metz Fresh conducts on all of its products. Through its labeling and numbering system, Metz Fresh has already tracked, located and put 'holds' on the vast majority of the cartons of spinach affected. That spinach will not be released into the marketplace.

While the positive test came from only one sample of many on three packing lines, Metz Fresh has, as a precaution, chosen to recall all of the spinach from the 'field lot' packed that day on all three lines.

Metz Fresh is keeping appropriate authorities updated on the status of the voluntary recall.

####

Photo: Metz Fresh Spinach

FDA's Pilot Program to Better Educate Consumers about Recalled Food Products

RSS Feed for FDA Recalls Information [what's this?]

DHCS Home

CDPH Home

Printer Friendly Version

Drug Safety Program

Export Document Program

Organic Processed Products Program

Food Safety Program

Home Medical Device Retail Program

Medical Device Safety Program

S.T.A.K.E. Program

Sherman Food, Drug, and Cosmetic Law (pdf)

Application Instructions and Forms

Consumer Complaints

Comments and Questions

The Adobe Reader is required to view several documents contained on this website

Food and Drug Branch

Environmental Investigation Reports

Investigation of the Taco John's *Escherichia coli* O157:H7 Outbreak Associated with Iceberg Lettuce - Redacted

CDPH Investigation of a 2006 E. coli 0157: H7 Outbreak Associated with Taco Bell Restaurants in the Northeastern United States - Redacted (10 MB pdf)

ADDENDUM to CDHS investigation of an E. coli O157: H7 Outbreak Associated with Consumption of Dole Brand Pre-Packaged Baby Spinach Manufactured by Natural Selection Foods: September 2006 - March 2007 (pdf)

CDHS investigation of an E coli O157 H7 Outbreak Associated with Consumption of Dole Brand Pre-packaged Baby Spinach Manufactured by Natural Selection Foods: September 13, 2006 – March 21, 2007 Redacted (file size = 6mb) (pdf)

CDHS Investigation of an E coli O157 H7 Outbreak Associated with Consumption of Dole Brand Pre-packaged Baby Spinach Manufactured by Natural Selection Foods: September 13, 2006 – March 21, 2007 Redacted with photos and figures removed (file size = 2mb) (pdf)

CDHS Recommendations in follow up to the Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach – March 2007 (pdf)

E. coli 0157:H7 Illnesses in Washington - July 2, 2002 (pdf)

Investigation *Salmonella* Enteritidis Phage Type 30 Outbreak Associated with Consumption of Raw Almonds - March 2001 - February 2002

Investigation of E. coli 0157:H7 Outbreak in San Mateo Retirement Facility - April 30, 2004 (pdf)

Investigation of E. coli 0157:H7 Illnesses in San Diego and Orange Counties - October 6, 2003 - May 17, 2004 (pdf)

Investigation of *Salmonella* Enteritidis Phage Type 9c Outbreak Associated with Consumption of Raw Almonds - May 14 to August 2, 2004 (pdf)

Coversheet for Addendum Report to "Investigation of Pre-washed Mixed Bagged Salad following an Outbreak of E.coli O157:H7 in San Diego and Orange County" - October 26, 2005 (pdf)

Addendum Report to "Investigation of Pre-washed Mixed Bagged Salad following an Outbreak of Escherichia coli O157:H7 in San Diego and Orange County" - October 26, 2005 (pdf)

Investigation of an E coli O157 H7 Outbreak Associated with Consumption of Dole Brand Pre Packaged Salads Redacted - October 1, 2005 - November 21, 2005 (pdf)

Investigation of E. coli O157:H7 outbreak linked to Fancy Cutt Farms - August 1996

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Publication Date 2-25-08
Certifier L. CLAWSON
DDM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA–2008–D–0108 (formerly Docket No. 2006D–0079)]

Guidance for Industry: Guide to Minimize Food Safety Hazards for Fresh-cut Fruits and Vegetables; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (the fresh-cut guidance or guidance). Previously, FDA announced the availability of the fresh-cut guidance as a "draft final" document, pending approval by the Office of Management and Budget (OMB) of the information collection provisions in the guidance. FDA is publishing this notice to announce that the fresh-cut guidance is now final. The text of the guidance has not changed from the previously published draft final version. The fresh-cut guidance complements FDA's current good manufacturing practice (CGMP) requirements for foods by providing specific guidance on the processing of fresh-cut produce. The fresh-cut guidance and the CGMP regulations are intended to assist processors in minimizing microbial food safety hazards common to the processing of most fresh-cut fruits and vegetables sold to consumers and retail establishments in a ready-to-eat form.

DATES: Submit written or electronic comments on the guidance at any time.

cf084

FDA-2008-D-0108

NAD

ADDRESSES: Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written requests for single copies of the guidance to the Office of Food Safety (HFS–317), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1700 or FAX: 301–436–2651. Send one self-addressed adhesive label to assist the Center in processing your request.

FOR FURTHER INFORMATION CONTACT: Rhoma Johnson, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2066 or FAX: 301–436–2651.

SUPPLEMENTARY INFORMATION:

I. Background

Fresh-cut fruits and vegetables are minimally processed fruits and vegetables that have been altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. The methods by which produce is grown, harvested, and processed may contribute to its contamination with pathogens and, consequently, the role of the produce in transmitting foodborne illness. Factors such as the high degree of handling and mixing of the product, the release of cellular fluids during cutting or chopping, the high moisture content of the product, the absence of a step lethal to pathogens, and the potential for temperature abuse in the processing,

storage, transport, and retail display all enhance the potential for pathogens to survive and grow in fresh-cut produce.

On March 6, 2006, FDA published in the **Federal Register** a notice entitled "Draft Guidance for Industry: Guide to Minimize Food Safety Hazards of Fresh-Cut Fruits and Vegetables" (71 FR 11209) (the March 2006 notice). FDA gave interested persons 60 days to comment on the draft guidance. The comment period closed on May 5, 2006. The draft guidance was revised based on public comments. The draft guidance contained information collection provisions subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). Under the PRA, Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, in the March 2006 notice (71 FR 11209), FDA gave interested persons 60 days to comment on the information collection provisions in the draft guidance. After providing the 60-day notice requesting public comment, section 3507 of the PRA (44 U.S.C. 3507) requires Federal agencies to submit the proposed collection to OMB for review and clearance. In compliance with 44 U.S.C. 3507, FDA submitted the proposed collection of information to OMB for review and clearance.

On March 13, 2007, FDA published in the **Federal Register** a notice announcing the availability of a "Draft Final Guidance for Industry: Guide to

Minimize Food Safety Hazards for Fresh-Cut Fruits and Vegetables" (72 FR 11364). This document was issued as a "draft final" guidance pending OMB approval of the collection of information. FDA announced OMB's approval of the collection of information in a notice published on October 19, 2007 (72 FR 59295). With OMB approval, FDA is publishing this notice announcing that the fresh-cut guidance is final and providing an OMB control number (See section II of this document).

The fresh-cut guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The fresh-cut guidance is intended to assist processors in minimizing microbial food safety hazards common to the processing of most fresh-cut fruits and vegetables sold to consumers and retail establishments in a ready-to-eat form. This guidance represents FDA's current thinking on the microbiological hazards presented by most fresh-cut fruits and vegetables and the recommended control measures for such hazards in the processing of such produce. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0609.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance document at any time. Submit a single copy of electronic comments or two paper copies

of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance document at the following Web site: *http://www.cfsan.fda.gov/guidance.html.*

Dated: 2/15/08
February 15, 2008.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

BILLING CODE 4160–01–S

Beef Industry, Animal Rights Groups Duel

By IVAN MORENO – 2 days ago

DENVER (AP) — The cattle industry and animal rights groups bickered over the treatment of beef destined for U.S. dinner plates a day after secret video triggered the nation's largest meat recall.

Undercover video taken at the Westland/Hallmark Meat Co. of Chino, Calif., shows workers shocking, kicking and shoving debilitated cattle with forklifts, prompting the government to pull 143 million pounds of the company's beef.

Bo Reagan, vice president of research for the Colorado-based National Cattleman's Beef Association, said the videotaped incident was not indicative of how most slaughterhouses operate.

"The welfare of our animals — that's the heart and soul of our operations," Reagan said.

U.S. Department of Agriculture guidelines mandate that an inspector review sick or injured animals, called "downer" cattle, before they can be slaughtered, and that the 1958 Humane Slaughter Act sets strict rules for the humane treatment of animals.

"What happened in this case was that there were some animals that were harvested out of compliance," he said.

Federal regulations call for keeping downed cattle out of the food supply because they may pose a higher risk of contamination from E. coli, salmonella or mad cow disease since they typically wallow in feces and their immune systems are often weak.

Wayne Pacelle, president and CEO of the Humane Society of the United States, which videotaped the alleged abuse, said his organization chose to investigate the Westland/Hallmark plant at random, and said he was skeptical of the cattle industry's practices.

"I think this is the typical rhetorical and typical false assurances that we hear from the industry after glaring problems have been exposed," he said.

Pacelle said it's impossible to say whether the treatment depicted on the video is isolated, but stopped short of calling it widespread.

"I think we can't say for sure one way or another, but it's certainly a bad sign for the industry and the USDA to have been exposed for their failures in this single, random investigation," he said.

The recall affects beef products dating to Feb. 1, 2006. Agriculture officials estimate that about 37 million pounds of the recalled beef went to school programs, but they believe most of the meat probably has already been eaten.

"We don't know how much product is out there right now. We don't think there is a health hazard, but we do have to take this action," said Dr. Dick Raymond, USDA undersecretary for food safety.

Rep. Rosa L. DeLauro, chairwoman of the House Agriculture, Food and Drug Administration Appropriations Subcommittee, called the video inhumane and said she was concerned it "demonstrates just how far our food safety system has collapsed."

DeLauro, D-Conn., has also called for an independent investigation into the government's ability to secure the safety of meat in the nation's schools.

Recalled meat is piling up in at least seven Michigan school districts. Grand Rapids Public Schools must throw out 10 tons of hamburger, while the Ann Arbor Public Schools has about 200 pounds of the beef. The Detroit Public Schools system got a shipment of 150 cases of frozen chili and taco meat, but officials say none of it was eaten.

Some of the hamburger being recalled already was served to students in Portage Public Schools. "It was in our taco sauce and our spaghetti sauce," Portage district food service manager Lance Gerry told the Kalamazoo Gazette. "We've been serving those products for a while."

USDA spokesman Keith Williams said his department has evidence that Westland did not routinely contact its veterinarian when cattle became non-ambulatory after passing inspection, violating health regulations.

Williams said the recall was done primarily to revoke the USDA's seal of inspection for the meat — not because of the risk of illness.

"Everybody's going 'Oh, a recall, that means death, that means sickness.' That's a different kind of issue," Williams said. "This is a lower severity, where there would be a remote probability of sickness."

DeLauro also asked what the USDA is doing to address staff shortages among slaughterhouse inspectors — an issue also raised by other food safety experts and watchdog groups Monday.

Washington-based Food and Water Watch said the USDA has left up to 21 percent of inspector positions vacant in some areas. Williams, of the USDA, said there is no shortage of inspectors.

Two former Westland/Hallmark employees were charged Friday. Five felony counts of animal cruelty and three misdemeanors were filed against a pen manager. Three misdemeanor counts — illegal movement of a non-ambulatory animal — were filed against an employee who worked under that manager. Both were fired.

One of the men, Daniel Ugarte Navarro, was arrested Saturday at his home in Pomona, Calif., and was released on $7,500 bail, Chino police spokeswoman Michelle Vanderlinden said Tuesday. He could face up to 5 years and 8 months in prison, if convicted, she said.

The second man, Luis Sanchez, 32, of Chino, remained at large Tuesday, San Bernardino County Deputy District Attorney Debbie Ploghaus said.

No charges have been filed against the company, but an investigation by federal authorities continues. A phone message seeking comment Tuesday from Westland/Hallmark president Steve Mendell was not returned.

Associated Press writers Gillian Flaccus and Jacob Adelman and AP videographer John Mone in Los Angeles contributed to this report.

THE WALL STREET JOURNAL. ONLINE

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February 25, 2008

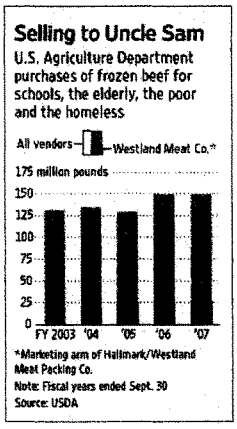
PAGE ONE

Meatpacker in Cow-Abuse Scandal May Shut as Congress Turns Up Heat

By DAVID KESMODEL and JANE ZHANG
February 25, 2008; Page A1

CHINO, Calif. -- Last year, a man carrying a hidden video camera took a $12-an-hour job at a little-known beef slaughterhouse here. Now the meatpacker is about to collapse, and has become a flashpoint in a national debate over meat safety and the quality of food Americans serve their schoolchildren.

Hallmark/Westland Meat Packing Co., one of the biggest suppliers of beef to the national school-lunch program before videos showing animal cruelty at the plant helped trigger the biggest meat recall in U.S. history, probably will shut down permanently, according to the company's general manager, Anthony Magidow.



The company's president and owner, Steve Mendell, hasn't responded to requests for comment, and its controller, Juan Acevedo, referred an interview request to Mr. Magidow.

"I don't see any way we can reopen," Mr. Magidow said in a telephone interview. The closely held company, which had about $100 million a year in sales, is starting to run low on cash, he said.

Hallmark/Westland struggled for years, but it began turning a profit consistently after being approved by the U.S. Department of Agriculture to begin supplying beef for the federal school-lunch program in 2003, Mr. Magidow said. Within two years, it was supplying about 25 million pounds of beef a year to the program through competitive bidding.

Only 23 of the about 900 boneless beef suppliers in the U.S. are approved to supply such USDA commodity-purchase programs, said Les Johnson, a consultant and former director of the food-distribution division of USDA's Food and Nutrition Service.

To qualify, each facility must have its financial statements reviewed, be federally inspected, receive visits from USDA officials to examine plant processes and equipment and submit a technical explanation about how the plant does everything from controlling germs to testing the fat content of its products.

For the 2004-05 school year, the government named Hallmark/Westland the school lunch program's Supplier of the Year. But the company began to unravel in late January, when a video made by an investigator from the Humane Society of the U.S. came to light.

The video showed workers at the plant trying to make sick or injured cattle stand up with electrical-shock devices, forklifts and high-pressure water hoses. Cattle that can't walk or stand on their own are generally banned from the nation's food supply. Such "downer" cows can be sources of mad-cow disease, which can cause a rare but fatal brain disorder in humans.

The video "just astounded us," Mr. Magidow said Friday. "Our jaws dropped....We thought this place was sparkling perfect."

The company closed voluntarily, fired two workers and began taking steps to be reauthorized to resume operations. But Mr. Magidow said additional Humane Society video provided to the USDA apparently gave the agency ammunition to issue a recall of 143 million pounds of beef produced by the plant, dating back as far as February 2006. (Watch that video.[1])

Citing the continuing investigation, a USDA spokeswoman declined to say what evidence spurred the agency to act.

Debate in Congress

The scandal has triggered a heated debate in Congress and elsewhere over the safety of the U.S. meat supply, as well as criticism of both the company and the USDA, which had inspectors stationed at the plant. Lawmakers in Washington and Sacramento have scheduled hearings starting this week to explore how the problem occurred despite the presence of federal inspectors, whether the USDA is doing its job, and whether the meat supplied to the school-lunch program is safe.

On Thursday, Sen. Herb Kohl, a Wisconsin Democrat who heads an agriculture appropriations subcommittee, plans to hold a hearing to address, among other things, "serious questions on risks posed to children by the recalled beef," his office said. Secretary of Agriculture Ed Schafer and James Hodges, president of the American Meat Institute Foundation, an industry trade group, are expected to attend.

Hallmark/Westland, meanwhile, has been deluged with hundreds of emails by consumers furious about the video, says Mr. Magidow. He says the recall is too extreme in scope, and that the company is being unfairly maligned, because there is no evidence that any of the recalled meat was contaminated.

The USDA says no one has gotten sick from the meat and that there is very little risk of harm from consuming it.

The company fired the two workers shown in the video that the Humane Society released in January. Daniel Ugarte Navarro, a 49-year-old former cattle-pen manager at the plant, faces the possibility of more than five years in prison on felony and misdemeanor charges of animal cruelty, said Deborah Ploghaus, deputy district attorney in San Bernardino County. Luis Sanchez, 32, who worked for Mr. Navarro, faces three misdemeanor charges.

Efforts by The Wall Street Journal to reach the two men were unsuccessful. The daily Press-

Enterprise in Riverside, Calif., quoted a woman who identified herself as Mr. Sanchez's wife denying that her husband had done anything illegal. The paper also spoke with Mr. Navarro's wife, but she declined to comment.

Mr. Navarro was a supervisor with some 30 years of experience, Mr. Magidow said. He said Mr. Navarro dealt directly with USDA inspectors conducting audits, as well as private companies that bought meat from the plant and conducted their own audits.

Suspended Operations

After the video was released, the USDA launched an investigation into the plant's practices, and the company voluntarily suspended operations. The plant began trying to address its problems so it could resume production, Mr. Magidow said. Among other steps, it hired Arrowsight, a Mount Kisco, N.Y., monitoring company, to help it step up surveillance. The company installed about 15 video cameras throughout the slaughterhouse to help monitor activities.

Arrowsight couldn't be reached for comment.

Leading up to the weekend of the recall, Feb. 16-17, "We were starting to do all the things necessary" to be reauthorized, Mr. Magidow said. "We were doing everything we could to make sure we had the foremost facility."

But that weekend, in a phone call to Hallmark/Westland's president, Mr. Mendell, at 1 a.m. West Coast time, the USDA informed the meatpacker that new evidence had emerged that suggested a significant violation of USDA safety rules and the need for a massive recall. It was the additional undercover video shot by the Humane Society, Mr. Magidow said. He said he hasn't seen the video, but said company officials have been told that it shows an animal that had fallen down before entering the "kill" or "knocking" box, where the animals are slaughtered. The animal is about "half in, half out" of the box, he said.

Wayne Pacelle, the Humane Society's president, confirmed that description of the video.

The video apparently showed only one cow in such a situation, Mr. Magidow said. But the USDA interviewed an employee who worked on the slaughtering line who told them that, on rare occasions, the company went ahead and slaughtered an animal that had stumbled prior to slaughter after initially being cleared for slaughter by inspectors. The company is supposed to first contact a USDA inspector in such situations.

The employee told USDA officials that he had followed instructions from Mr. Navarro that if an animal had slipped prior to reaching the kill box but was otherwise a normal, ambulatory animal, to go ahead with the slaughter, according to Mr. Magidow. The employee began working at the company in February 2006; that became the start date of the recall.

"We are going by what we were told, we have not been allowed to see the video," Mr. Magidow said.

The USDA has said it received new evidence that led to the recall covering two years, but it has declined to disclose the details, because its investigation is pending. "We know that it was a very rare occurrence," USDA official Kenneth Petersen told reporters last week, "but obviously, given that we went back two years, we obviously have some reason to believe that it occurred with some

frequency over the last two years."

The initial video didn't provide specific evidence that downer cattle may have been slaughtered, though it shows animal cruelty.

After being approved for slaughter, cattle must walk up a serpentine 90-foot chute, on an incline, before being killed, Mr. Magidow said. The chute meanders in part so that cattle won't suspect what is about to happen to them, he said. The incline helps ensure that only cattle able to walk and stand on their own can make it to the slaughtering line.

--Elizabeth Williamson contributed to this article.

Write to David Kesmodel at david.kesmodel@wsj.com[2] and Jane Zhang at Jane.Zhang@wsj.com[3]

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(2) mailto:david.kesmodel@wsj.com
(3) mailto:Jane.Zhang@wsj.com

[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	11/26/2007 - 02/15/2008
	FEI NUMBER 1511662

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Rick P. Ray, President

FIRM NAME	STREET ADDRESS
New Era Canning Company	4856 1st St.
CITY, STATE AND ZIP CODE (COUNTRY)	TYPE ESTABLISHMENT INSPECTED
New Era, MI 49446-9608	LACF Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Failure to identify, from processor check or otherwise, deviations from the scheduled process or critical factors which are out of control.

Specifically, your firm failed to identify process deviations including lots of product manufactured in both your [redacted] Retorts and [redacted] Retorts prior to 11/28/07.

A. Your firm manufactured low acid canned foods in No. 10 cans including green beans and garbanzo beans which were found to contain viable *Clostridium botulinum* spores through FDA sample analysis. The sampled lots that were found to contain viable spores include the following:

Product	Lot No.	Mfr. Date	Sampled	Can End Appearance
Green Beans	19H7FL	8/9/07	11/30/07	abnormal
Green Beans	2BH7FL	8/11/07	12/22/07	abnormal
Green Beans	26G7FQ	7/6/07	12/22/07	normal
Garbanzo Beans	34F7LG	6/4/07	12/22/07	normal and abnormal

B. Every lot of low acid canned food products that you produced in your [redacted] retorts prior to 11/28/07 is a process deviation because of the potential for underprocessing due to the possible buildup of condensate in the bottom of the retorts that could contact cans during processing. These deviations were not recognized by your firm and handled properly in accordance with 21CFR Part 113.89. Your firm routinely manufactures low acid canned food products in each of its [redacted] retorts, and did so on those dates identified in Observation 2 A.

C. You have failed to properly evaluate defective lots in a timely manner to assure there are no potential public health hazards associated with your finished products. Your firm's employees did not conduct a complete spoilage diagnosis to determine whether spoilage was due to under processing or post-process leakage. Corrective action was not taken in a timely manner to remove and destroy defective spoiled cans and to fix the problem causing the spoilage. Whole or portions of defective lots were observed with swells, buckles and/or defective seams in the warehouse. The following defective portions of finished lots were observed (in addition to those defective lots described in 1 A):

Mfr. Date	Observ. Date	Product	Can Size	Lot No.	Reason Held
6/7/07	12/4/07	Garbanzo Beans	No. 10	17F7LG	Still Cook

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Brian P. Hazelmeyer

Robert V. Chase Jr. and Rick

DATE SIGNED
02/15/2008

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[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
300 River Place, Suite 8950
Detroit, MI 48207
(313) 393-8100 Fax: (313) 393-8139

DATE(S) OF INSPECTION
11/26/2007 - 02/15/2008*

FEI NUMBER
1811662

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Rick P. Ray, President

FIRM NAME
New Era Canning Company

STREET ADDRESS
4856 1st St.

CITY, STATE, ZIP CODE, COUNTRY
New Era, MI 49446-9608

TYPE ESTABLISHMENT INSPECTED
LACF Manufacturer

6/14/07	11/30/07	Chili Beans	No. 300	AEF7LW	Low Vacuum
10/5/05	11/30/07	Pumpkin	No. 10	25J5IC	Buckles
10/12/07	11/29/07	Black Beans	No. 10	3CJ7LK	Buckles
10/12/07	11/29/07	Black Beans	No. 10	4CJ7LK	Buckles
5/31/07	11/30/07	Black Beans	No. 300	FVE7LK	Weight
11/16/07	1/4/08	Chili Beans	No. 10	4GK7LC	Process Deviation
11/26/07	1/24/08	Great Northern	No. 10	2QK7LE	0 vacuum, seam problems

D. According to your hold product reports and distribution records in 2005 and 2006, your firm debuckled cans of LACF products that exhibited evidence of buckling by using a hand press to push the can ends back into place. These debuckled cans were then released from hold status and made available for sale to your customers as follows:

Mfr. Date	Product	Lot No.	Retort	Reason Held	Disposition
3/3/06	Black Beans	23C6LK	FMC	100% Buckling	debuckled 3/27/06, labeled 4/25/07
3/3/06	Black Beans	13C6LK	FMC	100% Buckling	debuckled 3/27/06, labeled 4/25/07
12/7/05	Great Northern	27L5LE	FMC	Buckled, dented	debuckled, labeled 5/25/06
10/12/05	Pumpkin	1CJ5IH	Malo	Buckled	debuckled, labeled 10/26/05
10/8/05	Pumpkin	18J5IC	Malo	100% Buckling	labeled 11/2/06
10/7/05	Pumpkin	17J5IC	Malo	100% Buckled	labeled 11/2/06

OBSERVATION 2

The system, equipment, and procedures used for thermal processing of foods in hermetically sealed containers did not conform to the applicable requirements of 21 CFR 113.40 and were not operated and administered in a manner that ensures commercial sterility is achieved.

A. Specifically, your firm did not conduct temperature distribution studies on your [redacted] retorts after retrofitting new false bottom doors at the bottom of the retorts. New false bottoms were installed on Retorts [redacted] in 1982 and a new false bottom was installed on Retort No. 2 in 1992. The last temperature distribution study on your retorts was conducted on June 9, 1976. Your firm routinely manufactures LACF products in No. 300 and No. 10 cans in these crateless retorts. Some examples of lots produced include:

Mfr. Date	Product	Can Size	Lot Code
9/4/07	Black Beans	No. 300	A47L7K
9/29/07	Pumpkin	No. 300	AT17IC
10/6/07	Pumpkin	No. 300	E6J7IC
10/23/07	Pumpkin	No. 300	DNJ7IC
11/29/07	Garbanzo	No. 300	ATK7LG
10/5/05	Pumpkin	No. 10	25J5IC
10/8/05	Pumpkin	No. 10	18J5IC

B. In addition, your firm failed to conduct temperature distribution tests on both the [redacted] No. 10 can and 300 can retorts as evidenced by the lack of documentation supporting such tests. Low acid canned foods listed below have been processed in

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DATE ISSUED
02/15/2008

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[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	11/26/2007 - 02/15/2008
	FEI NUMBER 1811662

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Rick P. Ray, President

FIRM NAME	STREET ADDRESS
New Era Canning Company	4856 1st St.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New Era, MI 49446-9606	LACF Manufacturer

these retorts since their installation. Both cookers were purchased in used condition and were installed by your firm's employees (the No.10 cooker was installed in 1994 and the No. 300 can cooker was installed in 2002).

Mfr. Date	Product	Can Size	Lot Code
6/7/07	Garbanzo Beans	No. 10	37F7LG
8/9/07	Green Beans	No. 10	19H7FL
11/26/07	Great Northern	No. 10	1QK7LE
8/11/07	Green Beans	No. 10	2BH7FL
7/6/07	Green Beans	No. 10	26G7FQ
5/9/07	Green Beans	No. 300	B9G7HA
9/18/07	Green Beans	No. 300	DI17HM
9/18/07	Green Beans	No. 300	EI17HM
6/7/07	Dark Red Kidney Beans	No. 300	C7F7LD

OBSERVATION 3

Failure to install bleeders so that the operator can observe that they are functioning properly.

Specifically, your system for monitoring the buildup of condensate at the bottom of your [redacted] retorts is not effective in that the bottom condensate bleeder, in the false bottom door, is not visible to the retort operator. There are no other monitoring devices in place beneath the false bottom to alert the retort operator to the buildup of condensate at levels high enough to contact cans during processing.

Your firm uses [redacted] retorts to manufacture LACF products on a routine basis and produced the following lots under conditions described above on the following dates:

Date	Product	Can Size	Lot Code
9/4/07	Black Beans	No. 300	A4I7LK
9/26/07	Pumpkin	No. 300	CQI7IC
9/29/07	Pumpkin	No. 300	ATI7IC
10/6/07	Pumpkin	No. 300	E6J7IC
10/9/07	Pumpkin	No. 300	C9J7IC
10/23/07	Pumpkin	No. 300	DNJ7IC
11/5/07	Pumpkin	No. 300	A5K7IC

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	11/26/2007 - 02/15/2008
	FEI NUMBER 1811662

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Rick P. Ray, President

FIRM NAME	STREET ADDRESS
New Era Canning Company	4856 1st St.
CITY, STATE AND ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New Era, MI 49446-9608	LACF Manufacturer

OBSERVATION 4

Failure to use water which is safe and of adequate sanitary quality in food and on food-contact surfaces.

Specifically, FDA analysis of water samples collected on 1/10/08 revealed viable *Clostridium botulinum* spores at the following sampling points: the surge tank serving the atmospheric and pressure cooling shells of the [redacted] No. 10 [redacted] Retort; the water inlet line of the cooling canal serving the [redacted] Retorts; and the well heads at well numbers 1, 2, 3 and 4. Four production lots of bean products, identified in Observation 1 A, were cooked and subsequently cooled utilizing this same water supply and were found to contain viable *Clostridium botulinum* spores through FDA sample collection and analysis.

OBSERVATION 5

Plumbing constitutes a source of contamination to food and water supplies.

Specifically, the following plumbing-related observations were identified:

A. Well No. 4's discharge line located outside of the plant approximately [redacted] mile south of the your firm's warehouse was observed on 1/9/08 to be broken as evidenced by the visible caving of surface soils over the break which resulted in an approximate 7' diameter and 4' deep depression. Your firm has no information on how long the No. 4 well discharge line had been leaking prior to its discovery or whether the well No. 4 discharge line's direct connection to well No. 3's discharge line could have allowed the water that had escaped into the soil around the break to be siphoned back into the potable water stream by the flow of well No. 3.

B. Potable water line dead legs:

1) Two sections of galvanized metal pipe, one measuring approximately 14" long and 5" in diameter and another measuring approximately 50" long and 5" in diameter were observed on 1/9/08 as dead legs off of the 6" in-feed line where it enters the plant.

2) A section of approximately 50' of ½" diameter galvanized metal pipe connected in line and above the [redacted] retort cooling canal's 2" diameter galvanized metal pipe water supply line (located adjacent to [redacted] Retort No. 6) was observed on 1/10/08 as a dead leg. The 2" diameter galvanized metal pipe water supply line served as a FDA sampling point for potable water discharge and tested positive for viable *Clostridium botulinum* spores through FDA analysis.

3) An approximate 50' section of 2" diameter (ultimately reduced down to ¾" diameter) galvanized metal pipe attached to the ceiling above the apple peeler line was observed on 1/10/08 as a dead leg.

4) An approximate 30' section of [illegible]" diameter galvanized metal pipe attached to the ceiling above the apple sauce

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TYPED OR PRINTED NAME AND TITLE OF INVESTIGATOR(S)

DATE ISSUED
12/18/2008

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[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	11/26/2007 - 02/15/2008
	FEI NUMBER 1811662
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: Rick P. Ray, President	
FIRM NAME New Era Canning Company	STREET ADDRESS 4856 1st St.
CITY, STATE AND ZIP CODE, COUNTRY New Era, MI 49446-9608	TYPE ESTABLISHMENT INSPECTED LACF Manufacturer

line was observed on 1/10/08 as a dead leg.

C. A submerged 1½" galvanized metal water inlet pipe located above the [redacted] No. 10 [redacted] Retort recirculation tank and serving the atmospheric and pressure cooling shells of the [redacted] No. 10 [redacted] Retort was observed on 1/9/08.

D. Well No. 3's casing was observed on 1/9/08 to terminate in an undrained well pit [redacted] and Well No. 4's vent screens were observed laden with dust and debris.

E. On 1/29/08, a 2" diameter galvanized potable water line (labeled "FRESH WATER") was observed being inter-connected by means of a single check valve with the water line from the [redacted] No. 10 [redacted] Retort's open recirculation tank.

OBSERVATION 6

Failure to have a qualified individual perform teardown examinations of double seam cans .

Specifically, you have manufactured multiple production lots of LACF products with loose double seams for the following reasons:

A. Your can supplier's spoilage diagnostic report dated 12/19/07 disclosed that 17 No. 10 cans (nine buckled and eight normal) of pumpkin, green beans and garbanzo beans all had loose seams with wrinkle ratings ranging from 50 to 70 where the minimum specification for cover hook wrinkle is [redacted]. Four of the nine buckled cans leaked at the packer's end when subjected to an under water pressure test and 1 of the normal (flat appearing) cans leaked when subjected to the same test. The lots represented by these 17 cans were field examined and sampled by FDA because of swells and buckles in the lots.

B. FDA's observations of six tear down examinations of No. 10 cans of great northern beans and two teardown examinations of No. 10 cans of applesauce in your plant on 1/4/08 revealed the following: wrinkle ratings ranged from 50 to 75 on the cover hooks from three of six cans of great northern beans and [redacted] cans of applesauce. The wrinkle ratings of the same cover hooks recorded by your seam inspectors ranged from 85 to 95.

In addition, the overlap (OL) measurements of double seams of your No. 10 cans of finished LACF products were consistently less than the minimum specification of [redacted] when the OL calculation used worst case measurements of the shortest cover hook (CH), the shortest body hook (BH) and the longest seam width (W). For example, when worst-case measurements were used, five of six cans of great northern beans, lot 1QK7LE manufactured on 11/26/07 had OL readings ranging from 0.038 to 0.040; when average measurements of BH, CH & seam W were used, OL ranged from 0.051 to 0.054. These cans were selected for tear down examination from the held portion of the lot in your firm's warehouse and were torn down and examined by your own seam inspector.

C. Your can supplier serviced your [redacted] seamer at about 10:00 A.M. on 2/19/07 and found that [redacted] seaming heads were producing loose double end seams on No. 10 cans as evidence by cover hook wrinkle ratings of 60, 80 and 70. However, your can seam tear down records for this same seamer at 6:00 A.M. and again at 9:05 A.M. showed the [redacted] heads of this seamer producing tight seams meeting the can supplier's minimum specification with cover hook wrinkle

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	12/26/2007 - 02/15/2008* FEI NUMBER 1811862

TO: Rick P. Ray, President

FIRM NAME	STREET ADDRESS
New Era Canning Company	4856 1st St.
CITY, STATE & ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New Era, MI 49446-9608	LACF Manufacturer

ratings ranging from 80 to 95.

Your can supplier also serviced the same [redacted] seamer on 11/6/07 and on 8/28/07. On these dates the service representative found the seams loose on one of the [redacted] seaming heads and made the necessary adjustment to tighten the seams produced on this machine. However, your seam teardown records for 10/15/07 and 8/27&28/07 (production days on or prior to these service visits) do not document any loose seam problem with the [redacted] seamer or any adjustments made to this machine.

D. You have failed to properly maintain your [redacted] seamer to ensure the consistent production of hermetic seals. For example, lot No. 4GK7LC of chili beans manufactured on 11/16/07 contained numerous dead heads (observed on 1/22/07). Maintenance performed on this seamer to correct the problem on 11/16/07 was not effective because the same defects reoccurred during the production of great northern beans, lot Nos. 1QK7LE and 2QK7LE, on 11/26/07 (observed on 1/24/08). Your can seam visual and tear down evaluation records for these two production dates did not exhibit evidence of a dead heading problem.

E. On approximately 2/5/08, your firm's consultant tore down and examined 114 two-piece 300 x 407size cans and 36 three-piece welded 307x 409 size cans and found failures to meet the can manufacturer's minimum specification for overlap (OL) and tightness (T) as follows:

Size can	Failure to meet mfin. Tightness (T) failed of sampled	%	Failure to meet Min overlap (OL) failed of sampled	%
300x407	18 of 114	[redacted]	11 of 114	[redacted]
307x409	12 of 36		0 of 36	

OBSERVATION 7

Failure to chlorinate or otherwise sanitize container cooling water as necessary for cooling canals and recirculated water supplies.

Specifically, the cooling canal below your [redacted] retorts is not consistently treated and monitored for free residual chlorine. Five out of seven production records reviewed for canned pumpkin during the time period of 9/4/07 to 11/5/07 lacked evidence that the canal below the [redacted] retorts was monitored for free residual chlorine. Canned pumpkin was manufactured as described above on the following dates:

Date	Product	Can Size	Lot Code
9/29/07	Pumpkin	No. 300	ATI7IC
10/6/07	Pumpkin	No. 300	E6J7IC
10/9/07	Pumpkin	No. 300	C9J7IC
10/23/07	Pumpkin	No. 300	DNJ7IC
11/5/07	Pumpkin	No. 300	A5K7IC

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	11/26/2007 - 02/15/2008 FEI NUMBER 1811662
TO: Rick P. Ray, President	
FIRM NAME New Era Canning Company	STREET ADDRESS 4856 1st St.
CITY, STATE, ZIP CODE, COUNTRY New Era, MI 49446-9608	TYPE ESTABLISHMENT INSPECTED LACF Manufacturer

OBSERVATION 8

Bleeders are not wide open during the entire process and not open during come-up-time.

Specifically, on 1/10/08 all of the [redacted] bleeders (each measuring 1 1/64 inch inside diameter) along the top of the No. 10 can cooker shell were closed half way as evidenced by the ball valve control lever positioned at a 45 degree angle to the flow of steam. The control levers on five of these [redacted] bleeders were stuck at an approximate 45 degree angle and could not be turned by hand. According to your firm's management, these bleeders were never previously opened during processing. Many LACF products have been processed in this retort since its installation in 1994 with no temperature distribution data available to support the use of the half-closed bleeders during processing. Examples of LACF products manufactured under these conditions are listed in Observation 2 B.

OBSERVATION 9

A system of traffic control to prevent unretorted product from bypassing the retort system has not been established.

Specifically, your retort traffic control system and equipment design does not prevent uncooked cans from becoming co-mingled with cooked cans.

A. The following examples demonstrate that uncooked cans have been co-mingled with cooked cans:

1) On 3/15/07, your "Scoresheet for Dry Beans" indicates that during the production of small red kidney beans in 300 size cans, uncooked cans fell into the [redacted] canal. Two uncooked cans coded CFC7LW mixed with cooked cans of lot BFC7LW. According to your documentation, only one of the cans with the CFC7LW code was recovered.

2) On your Hold Product Report Reference No. H14906 dated 9/19/06, the hold description indicates that a possible raw product can was in the canal under the [redacted] Lot AJI6LV was held for the reason of unprocessed cans in the lot.

3) Your Certificate of Destruction of Food Products for Hold Tag No. H40207, dated 12/19/07 indicates the reason for destruction of small red kidney beans, lot BIL7LW, manufactured 12/18/07, as possible uncooked can.

4) Lot No. AIL7L6 of medium chili beans, processed in [redacted] Retort numbers [redacted] and [redacted] on 2/18/07, was held from shipping under Hold Product Report Reference No. H40107 because of a possible uncooked can that may have fallen from above the retort into the cooling canal below.

B. The following design failures observed relating to the [redacted] Retorts could allow unprocessed cans to commingle with cooked cans:

1) An approximate 3 ½ in. gap between the top surface of the retort and the bottom of the metal fencing surrounding the top door of all [redacted] orts can allow uncooked No. 300 cans to pass through a gap and fall into the cooling canal below, where finished cooked cans are conveyed. [redacted]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139	11/26/2007 - 02/13/2008
	FEI NUMBER 1811662
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: Rick P. Ray, President	
FIRM NAME	STREET ADDRESS
New Era Canning Company	4856 1st St.
CITY, STATE AND ZIP CODE/COUNTRY	TYPE ESTABLISHMENT INSPECTED
New Era, MI 49446-9608	LACF Manufacturer

2) The divert gate on four of the [redacted] retorts did not operate properly on 1/10/08. The gate on Retort numbers [redacted] would not open or close on a consistent basis due to jamming caused by the gate bending out of alignment when the operator manually pulled the control rope. Each time there was a jam, the operator had to climb on top of the retort to bend the gate back into alignment so it would work properly. [redacted]

3) The top door on each of your [redacted] retorts can be opened by the retort operator during the cooling cycle of a batch when the retort pressure is reduced to between 0 and about 5 psig. This could allow unprocessed cans of LACF on the conveyor feeding the [redacted] retorts to fall through the open door into the retort. These unprocessed cans would bypass the retort by being discharged along with the previous processed batch into the cooling canal below.

4) On 11/26/07 the metal chute supplying uncooked cans to Retort No. 1 was compromised by corrosion allowing cans enough space to fall into the finished product discharge/cooling canal beneath the [redacted] retorts. In addition, a gap was observed on each side of your inclined can conveyor feeding cans onto a second conveyor running along the top of the bank of [redacted] retorts. These gaps were large enough to allow a No. 300 can to pass through and fall into the cooling canal below.

Your [redacted] retort maintenance log states that the top door of [redacted] Retort No. [redacted] was not opening and closing properly on 5/10/07, 5/16/07 and 5/24/07. During the period 5/10-24/2007 your firm processed a total of [redacted] retort loads of garbanzo beans, dark red kidney beans, light red kidney beans and pinto beans in your [redacted] Retort No. [redacted] Examples of products produced on Retort No. [redacted] during this same period include:

TABLE 1. PRODUCTS MANUFACTURED IN [redacted] RETORT NO. 3

Product	Lot No.	Can Size	Mfr. Date
Garbanzo Beans	CAE7LG	No. 300	5/10/07
Garbanzo Beans	2GE7LG	No. 10	5/16/07
Light Red Kidney Beans	FDE7LL	No. 300	5/24/07
Asparagus	CNE7A	No. 300	5/23/07
Asparagus	DNE7A	No. 300	5/23/07
Asparagus	ENE7A	No. 300	5/23/07
Asparagus	FNE7A	No. 300	5/23/07

C. The following procedural deficiencies observed relating to the [redacted] Retorts could allow unprocessed cans to commingle with cooked cans:

1) Your processing records show that up to seven unprocessed cans in the in-feed track and valve preceding nine different batches of canned bean products were unaccounted for following the removal of still cooked cans from your No. 10 [redacted] retort after processing. These unprocessed cans are located outside the retort in the in-feed track and valve and are run through the retort with the still cooked cans after processing.

2) Your processing records show that up to five unprocessed No. 300 cans in the in-feed track and valve preceding one batch of still cooked beans were unaccounted for following the removal of the still cooked cans from your No.

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02/13/2008

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[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139	11/26/2007 - 02/13/2008 FEI NUMBER 1311662

TO: Rick F. Ray, President

FIRM NAME	STREET ADDRESS
New Era Canning Company	4856 1st St.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New Era, MI 49446-9608	LACF Manufacturer

300 can[redacted] cooker after processing. These unprocessed cans were located outside the retort in the in-feed track and valve and are run through the retort with the still cooked cans after processing.

TABLE 2. PRODUCTS MANUFACTURED IN [redacted] RETORTS

Product	Lot No.	Can Size	Mfr. Date
Green Beans	6FG5GA	No. 10	7/15/05
Green Beans	4OH5JM	No. 10	8/24/05
Green Beans	2315GM	No. 10	9/3/05
Chili Beans	5AJ6LC	No. 10	10/10/06
Kidney Beans	CKJ6LD	No. 300	10/20/06
Garbanzo Beans	1GE7LG	No. 10	5/16/07
Garbanzo Beans	34F7LG	No. 10	6/4/07
Chili Beans	1FF7LC	No. 10	6/15/07
Green Beans	19H7FL	No. 10	8/9/07
Green Beans	2BH7FL	No. 10	8/11/07

OBSERVATION 10

The condensate bleeder was not checked with sufficient frequency to ensure removal of condensate or equipped with an automatic alarm system for the continuous monitoring of condensate bleeder functioning.

Specifically, a condensate drain pipe with an approximate 2-inch diameter, on the No. 300 ca[redacted]retort was routed about 75 feet through a wall to a drain in an adjoining room and was not visible to the retort operator. The lack of visibility of this drain could affect the ability of the retort operator to monitor the build-up of condensate in the bottom of the retort during processing. Examples of LACF products manufactured under these conditions in this retort are listed in Observation 2 B.

OBSERVATION 11

Each container is not marked with an identifying code specifying the establishment where the product was packed.

Specifically, from 7/10/07 until 12/6/07, your firm discontinued use of your FCE number in your end can code and began using a descriptive text, which lacked identification of place of pack. The failure to identify the manufacturer in the product code could interfere with your firm's ability to recall product. Your firm routinely manufactures LACF products in each of its [redacted] crateless retorts and [redacted] retorts and packs products under your own label as well as under a number of private labels. The following production lots were manufactured with an end can code with a descriptive text instead of a code that identifies the production establishment:

Product	Lot No.	Mfr. Date	End Can Code
Green Beans	19H7FL	8/9/07	GREEN 19H7FL

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[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
300 River Place, Suite 5900
Detroit, MI 48207
(313) 393-8100 Fax: (313) 393-8139

DATE(S) OF INSPECTION
11/26/2007 - 02/15/2008*

FEI NUMBER
1811662

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Rick P. Ray, President

FIRM NAME
New Era Canning Company

STREET ADDRESS
4656 1st St.

CITY, STATE, ZIP CODE, COUNTRY
New Era, MI 49446-9608

TYPE ESTABLISHMENT INSPECTED
LACF Manufacturer

Green Beans	2BH7FL	8/11/07	GREEN 2BH7FL
Chili Beans	4GK7LC	11/16/07	CHILI 4GK7LC
Great Northern	1QK7LE	11/26/07	NORTH 1QK7LE
Great Northern	2QK7LE	11/26/07	NORTH 2QK7LE

OBSERVATION 12

Failure to mark each hermetically sealed container of low-acid processed food with an identifying code that is permanently visible to the naked eye.

Specifically, some of your canned bean products did not bear a product lot code. For example, the following lots of product were manufactured at your facility, and some part of each lot was found to be lacking a visible code:

Product	Lot No.	Mfr. Date
Green Beans	24H7FG	8/4/07
Green Beans	25G7FQ	7/5/07
Green Beans	3JG7FA	7/19/07
Green Beans	4OH5JM	8/24/05

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[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 8900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	11/26/2007 - 02/15/2008*
	FEI NUMBER 1811662

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Rick P. Ray, President

FIRM NAME	STREET ADDRESS
New Era Canning Company	4656 1st St.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New Era, MI 49446-9608	LACF Manufacturer

* DATES OF INSPECTION:
11/26/2007(Mon), 11/27/2007(Tue), 11/28/2007(Wed), 11/29/2007(Thu), 11/30/2007(Fri), 12/03/2007(Mon), 12/04/2007(Tue), 12/05/2007(Wed), 12/20/2007(Thu), 12/21/2007(Fri), 12/22/2007(Sat), 12/23/2007(Sun), 12/27/2007(Thu), 12/28/2007(Fri), 12/29/2007(Sat), 12/31/2007(Mon), 01/02/2008(Wed), 01/03/2008(Thu), 01/04/2008(Fri), 01/08/2008(Tue), 01/09/2008(Wed), 01/10/2008(Thu), 01/11/2008(Fri), 01/15/2008(Tue), 01/16/2008(Wed), 01/17/2008(Thu), 01/18/2008(Fri), 01/21/2008(Mon), 01/22/2008(Tue), 01/23/2008(Wed), 01/24/2008(Thu), 01/28/2008(Mon), 01/29/2008(Tue), 02/08/2008(Fri), 02/12/2008(Tue), 02/14/2008(Thu), 02/15/2008(Fri)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

300 River Place, Suite 8900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139	DATE(S) OF INSPECTION 11/26/2007 - 02/15/2008
	FEI NUMBER 1811662
TO: Rick P. Ray, President	
NAME New Era Canning Company	STREET ADDRESS 4856 1st St.
CITY, STATE, ZIP CODE, COUNTRY New Era, MI 49446-9608	TYPE ESTABLISHMENT INSPECTED LACF Manufacturer

Robert G. Taylor, Investigator

Ryan J. Benedict, Investigator

LTJG Aaron B. Otis, Investigator

Kelli Wilkinson, Investigator

Rasha Bamieh, Investigator

Linda S. Jozefiak, Investigator

LT Skip A. Payne, Investigator

Nicholas L. Paulin, Investigator

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FORM FDA 483 (04/07) PREVIOUS EDITION IS OBSOLETE

UNSPECTIONAL OBSERVATIONS

PAGE 1 OF 13 PAGES

THE HUMANE SOCIETY
OF THE UNITED STATES

Downers, Human Health Hazards and USDA Policy

An investigation by The Humane Society of the United States at a cattle slaughter plant has documented that animals too sick or injured to stand or walk—called "downers" by industry— have been kicked, dragged with chains, shocked with electric prods, and pushed by forklifts in efforts to get them to their feet to pass U.S. Department of Agriculture (USDA) inspection. In fact, the sickest and most debilitated animals are tormented the most. Abusive handling practices further compound the pain the downed animals already suffer as a result of the injury or illness causing their immobility.

In addition to the cruel treatment of these animals, at least 12 of the 15 identified cases of bovine spongiform encephalopathy (BSE or "mad cow disease") in North America to date have reportedly involved non-ambulatory animals. The HSUS is concerned that the results of our investigation into practices at Hallmark Meat Packing in Chino, Calif. may indicate that taxpayers are subsidizing the cruel conduct through USDA commodity purchase programs such as the National School Lunch Program, which provide food to young children, the elderly and needy families. Not only is it possible that the USDA has turned a blind eye to routine violations, the agency may actually be rewarding this conduct with lucrative federal government contracts.

Health Risks Related to Downed Cows

According to the USDA's *Federal Register* notice on January 12, 2004, "surveillance data from European countries in which BSE has been detected indicate that non-ambulatory cattle are among the animals that have a greater incidence of BSE than other cattle." The notice cited Swiss data showing a 49 to 58 times higher chance of finding BSE in downers than in cattle reported to veterinary authorities as BSE-suspect under passive surveillance. Downers may also be at higher risk for other foodborne transmissible pathogens, including *E. coli* and *Salmonella,* which kill hundreds of Americans every year, as these animals often lie in bacteria-laden waste and may have higher levels of intestinal pathogens due to stress. Infants, children and the elderly are more likely to experience severe illness requiring treatment and hospitalization as a result of both of these pathogens.

According to USDA, "Surveillance for BSE in Europe has also shown that the typical clinical signs associated with BSE cannot always be observed in non-ambulatory cattle infected with BSE because the signs of BSE often cannot be differentiated from the typical clinical signs of the many other diseases and conditions affecting non-ambulatory cattle." In other words, inspectors can't reliably determine the reason or reasons an animal became downed.

The consumption of meat from BSE-infected cattle can result in the development of variant Creutzfeldt-Jakob Disease (vCJD), a human spongiform encephalopathy. Described as "Alzheimer's in fast-forward," vCJD is a relentlessly progressive and invariably fatal dementia.

USDA Policy

Since 2000, USDA procurement specifications for beef used in the National School Lunch Program specifically prohibit the use of meat from downed animals.

On December 30, 2003, USDA announced: "Effective immediately, the USDA will ban all downer cattle from the human food chain." This announcement came one week after public disclosure of the first U.S.

case of BSE—a dairy cow in Washington state who was identified by a USDA veterinarian as downed due to calving injuries and later tested positive for BSE.

USDA has broadcast its no-downer policy as a key protective firewall against BSE. Most Americans had no idea that meat from animals too sick or injured to walk on their own could end up on their dinner plates. The agency's announcement helped ease public panic in the United States over the first BSE case and maintain consumer confidence both in the safety of the food supply and in the basic humane treatment of animals at slaughter plants.

Lack of Enforcement and an Unacceptable Loophole

In 2006, the USDA Office of the Inspector General (OIG) chastised the agency for its inconsistent application of policies and regulations related to downed animals after observing downers processed at several facilities that used forklifts and rails to transport the animals to the slaughter area. The OIG found that 29 downer cows were slaughtered for human food at a sample of 12 slaughter plants checked during a nine-month period. The audit noted the lack of documentation on the animals' fitness for consumption.

For years, USDA has publicly boasted about its comprehensive no-downer policy but circumvented it behind-the-scenes with a loophole that permits slaughter of some cows unable to walk. The agency has failed to follow its official interim policy published on January 12, 2004, which specified that **ALL** downer cattle would be excluded from the human food supply, "regardless of the reason for their non-ambulatory status or the time at which they became non-ambulatory. Thus, if an animal becomes non-ambulatory in [*sic*] route to the establishment due to an acute injury, it must be humanely removed from the truck, humanely euthanized, and the carcass properly disposed of. Likewise, cattle that become non-ambulatory on the establishment premises, such as an animal that breaks its leg as it is unloaded from the truck, are also required to be humanely moved, humanely euthanized, and the carcass properly disposed of."

In July 2007, USDA finally made permanent its so-called "ban" on slaughtering downer cattle, but in its announcement, the agency admitted that some downer cattle have been, and will continue to be, processed for human food. USDA's final rule specifies that "FSIS [USDA Food Safety and Inspection Service] inspection personnel will determine the disposition of cattle that become non-ambulatory after they have passed ante-mortem inspection on a case-by-case basis." In other words, cows who are able to walk when initially inspected by USDA but then keel over and cannot stand up again can nevertheless be slaughtered, and the meat can be sold.

This loophole is reckless from a public health perspective and exceedingly cruel.

A food safety system that relies on inspectors evaluating downers on a case-by-case basis is unworkable. Determining why an animal is down is challenging if not impossible for inspectors because injury and illness are often interrelated—e.g., a broken leg may simply be the observable result of the weakness, abnormal gait, or disorientation associated with an underlying disease. At least three of the documented cases of BSE in North America were identified as downers due to injury, not illness, showing how difficult it is for inspectors to reliably sort out which non-ambulatory animals are "safe." And even if "only" a broken leg is involved, dragging an animal with a fracture is just as cruel, if not more so.

USDA's lax enforcement of the downer rules has made its oversight virtually meaningless. As documented by The HSUS' undercover investigation, USDA inspectors may only conduct cursory observations, coming to check on animals just once or twice a day and disregarding their condition for the remaining hours.

USDA inspectors are required to monitor and verify humane handling in connection with slaughter, including offloading, holding and driving animals in pens and chutes. However, a USDA inspector was rarely present during offloading.

Solutions

A truly comprehensive ban on the use of any meat from downed animals in human food—with vigorous enforcement to ensure compliance—is needed to protect food safety and animal welfare. USDA must rewrite its rules to close the current loophole and redirect resources to provide adequate agency oversight.

A highly visible and vigorously enforced total no-downer rule would yield immediate benefits for schoolchildren, other consumers, and animals. It would also help in the long term to reduce animal suffering by creating an incentive for all involved in the production chain to minimize hazards that can cause animals to become downed in the first place. And it would remove current incentives that encourage workers to try every cruel tactic imaginable to move downers to the kill box. If downers can't be sold for food, there's no reason to prolong their misery.

1/30/2008